

Matter of Opioid Litig.
2018 NY Slip Op 31228(U)
June 18, 2018
Supreme Court, Suffolk County
Docket Number: 400000/2017
Judge: Jerry Garguilo
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SHORT FORM ORDER

INDEX No. 400000/2017

SUPREME COURT - STATE OF NEW YORK
NEW YORK STATE OPIOID LITIGATION PART 48 - SUFFOLK COUNTY

PRESENT:

E-FILE

Hon. JERRY GARGUILO
Justice of the Supreme Court

-----X	:	MOTION DATE <u>2/7/18</u>
	:	ADJ. DATE <u>3/21/18</u>
	:	Mot. Seq. #001 - MD
	:	Mot. Seq. #002 - MD
IN RE OPIOID LITIGATION	:	Mot. Seq. #004 - MD
	:	Mot. Seq. #005 - MD
	:	Mot. Seq. #007 - MotD
	:	Mot. Seq. #018 - MD
	:	Mot. Seq. #019 - MD
-----X		

Upon the reading and filing of the following papers in this matter: (1) Notice of Motion by defendants Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. (Mot. Seq. #001), dated November 10, 2017, and supporting papers (including Memorandum of Law); (2) Memorandum of Law in Opposition (Mot. Seq. #001), dated January 19, 2018; (3) Reply Memorandum of Law (Mot. Seq. #001), dated February 23, 2018; (4) Notice of Motion by defendants Purdue Pharma, L.P., Purdue Pharma, Inc., and the Purdue Frederick Company, Inc. (Mot. Seq. #002), dated November 10, 2017, and supporting papers (including Memorandum of Law); (5) Affidavit in Opposition by the plaintiffs (Mot. Seq. #002, #018, #019), dated January 18, 2018, and supporting papers (including Memorandum of Law); (6) Reply Memorandum of Law (Mot. Seq. #002), dated February 23, 2018; (7) Notice of Motion by defendants Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. (Mot. Seq. #004), dated November 10, 2017, and supporting papers (including Memorandum of Law); (8) Memorandum of Law in Opposition (Mot. Seq. #004), dated January 19, 2018; (9) Reply Memorandum of Law (Mot. Seq. #004), dated February 23, 2018; (10) Notice of Motion by defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. (Mot. Seq. #005), dated November 10, 2017, and supporting papers (including Memorandum of Law); (11) Memorandum of Law in Opposition (Mot. Seq. #005), dated January 19, 2018; (12) Reply Memorandum of Law (Mot. Seq. #005), dated February 23, 2018; (13) Notice of Motion by defendants Allergan plc and Actavis, Inc. (Mot. Seq. #007), dated November 10, 2017, and supporting papers (including Memorandum of Law); (14) Affidavit in Opposition by the plaintiffs (Mot. Seq. #007), dated January 19, 2018, and supporting papers (including Memorandum of Law); (15) Reply Memorandum of Law (Mot. Seq. #007), dated February 23, 2018; (16) Notice of Motion by defendants Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Allergan plc, and Actavis, Inc. (Mot. Seq. #018), dated November 10, 2017, and supporting papers (including Memorandum of Law); (17) Memorandum of Law in Opposition (Mot. Seq. #018), dated January 19, 2018; (18) Reply Memorandum of Law (Mot. Seq. #018), dated February 23, 2018; (19) Notice of Motion by defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (Mot. Seq. #019), dated November 10, 2017, and supporting papers (including Memorandum of Law); (20) Memorandum of Law in Opposition (Mot. Seq. #019), dated January 19, 2018; (21) Reply Memorandum of Law (Mot. Seq. #019), dated February 23, 2018; it is

ORDERED that the motion by defendants Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc., the motion by defendants Purdue Pharma, L.P., Purdue Pharma, Inc., and the

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Purdue Frederick Company, Inc., the motion by defendants Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc., the motion by defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc., the motion by defendants Allergan plc and Actavis, Inc., the motion by defendants Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Allergan plc, and Actavis, Inc., and the motion by defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc., are hereby consolidated for purposes of this determination; and it is

ORDERED that defendants' motions for an order pursuant to CPLR 3211, dismissing as against each and all of them the master form long complaint filed in this action, are granted to the limited extent set forth below, and are otherwise denied.

The plaintiffs are counties within the State of New York that have commenced separate actions against certain pharmaceutical manufacturers for harm allegedly caused by false and misleading marketing campaigns promoting semi-synthetic, opium-like pharmaceutical pain relievers, including oxycodone, hydrocodone, oxycodone, and tapentadol, as well as the synthetic opioid prescription pain medication fentanyl, as safe and effective for long-term treatment of chronic pain. Also named as defendants in those actions are certain pharmaceutical distributors that allegedly distributed those opium-like medications (hereinafter referred to as prescription opioids, pharmaceutical opioids, or opioids) to retail pharmacies and institutional health care providers for customers in such counties, and individual physicians allegedly "instrumental in promoting opioids for sale and distribution nationally" and in such counties. Briefly stated, the plaintiffs allege that tortious and illegal actions by the defendants fueled an opioid crisis within such counties, causing them to spend millions of dollars in payments for opioid prescriptions for employees and Medicaid beneficiaries that would have not been approved as necessary for treatment of chronic pain if the true risks and benefits associated with such medications had been known. They also allege that the defendants' actions have forced them to pay the costs of implementing opioid treatment programs for residents, purchasing prescriptions of naloxone to treat prescription opioid overdoses, combating opioid-related criminal activities, and other such expenses arising from the crisis.

One such lawsuit was commenced in August 2016 by Suffolk County and assigned to the Commercial Division of the Supreme Court. By order dated July 17, 2017, the Litigation Coordinating Panel of the Unified Court System of New York State directed the transfer of eight opioid-related actions brought by other counties, and any prospective opioid actions against the manufacturer, distributor, and individual defendants, to this court for pre-trial coordination. That same day, the undersigned issued a case management order reiterating that the individual actions are joined for coordination, not consolidated, and directing that a master file, known as "In re Opioid Litigation" and assigned index number 400000/2017, be established for the electronic filing of all documents related to the proceeding. The undersigned further directed the plaintiffs to file and serve a master long form complaint subsuming the causes of action alleged in the various complaints, and directed the manufacturer defendants, the distributor defendants, and the individual defendants to file joint motions pursuant to CPLR 3211, seeking dismissal of the master complaint, all by certain dates.

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The master long form complaint filed by the plaintiffs names as defendants the pharmaceutical manufacturers Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company, Inc. (collectively referred to as Purdue), Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. (collectively referred to as Cephalon), Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., n/k/a Janssen Pharmaceuticals, Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc. (collectively referred to as Janssen), Endo Health Solutions, Inc., and Endo Pharmaceuticals, Inc. (collectively referred to as Endo), Allergan plc f/k/a Actavis plc, Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively referred to as Actavis), and Insys Therapeutics, Inc. (referred to as Insys). Purdue allegedly manufactures, promotes, and sells various prescription opioids, including OxyContin and MS Contin, both of which are sold as extended release tablets and indicated for around-the-clock, long-term pain treatment, and Hysingla, which also is indicated for around-the-clock treatment of severe pain. Cephalon allegedly manufactures, promotes, and sells Actiq and Fentora, fentanyl drugs approved by the FDA for “breakthrough pain” in cancer patients who are tolerant to opioid therapy; it also allegedly sold generic opioids, including a version of OxyContin, from 2005 through 2009. Janssen allegedly manufactures, promotes, and sells Duragesic, a fentanyl drug approved for opioid-tolerant patients requiring around-the-clock opioid treatment, which is sold in the form of a transdermal patch. Until 2015, it also sold the prescription opioids Nucynta ER and Nucynta, both of which initially were approved for the management of moderate to severe pain, with Nucynta ER indicated for around-the-clock, long-term opioid treatment. Endo allegedly manufactures, markets, and sells the branded opioids Opana, Percodan, and Percocet, all three of which are marketed for moderate to severe pain, as well as generic opioids. Until June 2017, it also sold Opana ER, an oxymorphone drug in the form of an extended-release tablet, which was approved for around-the-clock treatment of moderate to severe pain, but it was removed from the market following a request by the FDA. Actavis allegedly markets and sells the branded drugs Kadian and Norco, and generic versions of Opana and Duragesic. Kadian, an extended-release morphine sulfate drug, allegedly is approved for the management of pain requiring around-the-clock, long-term treatment, and Norco is a generic version of Kadian. Insys allegedly develops, markets, and sells the branded prescription opioid Subsys, a sublingual spray of fentanyl.

As relevant to the motions that are the subject of this order, the master long form complaint (hereinafter the complaint) alleges that Purdue, Cephalon, Janssen, Endo, and Actavis (hereinafter collectively referred to as the manufacturer defendants), to maximize their profits, intentionally misrepresented to the public and the medical community the risks and benefits of opioids for the treatment of chronic pain. It alleges that to reverse the stigma historically associated with opioid use so that more patients would request opioids, more physicians would write prescriptions for them, and more healthcare insurers would pay for such treatment, the manufacturer defendants developed marketing campaigns, which included such strategies as branded and unbranded advertisements, educational programs and materials, and detailing of physicians, that overstated the benefits of prescription opioids for chronic pain (i.e., pain lasting three or more months) and misrepresented—even trivialized—the dangers associated with the long-term use of such medications. It further alleges that the defendants sold their pharmaceutical opioids to consumers within the plaintiffs’ jurisdictions.

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The complaint also names as defendants the pharmaceutical distributors McKesson Corporation, Cardinal Health, Inc., Amerisource Drug Corporation, American Medical Distributors, Inc., Belco Drugs Ltd., Kinray, LLC, PSS World Medical, Inc., and Rochester Drug Cooperative, Inc., and alleges that such defendants distributed pharmaceuticals to pharmacies and institutional providers within plaintiff counties. In addition, it names the physicians Russell Portenoy, Perry Fine, Scott Fishman, and Lynn Webster as defendants. The court notes that a stipulation discontinuing the claims against Dr. Portenoy without prejudice to any related action was filed by plaintiffs on March 16, 2018.

The complaint sets forth seven causes of action against all defendants. The first cause of action alleges deceptive business practices in violation of General Business Law § 349, and the second cause of action alleges false advertising in violation of General Business Law § 350. The third cause of action asserts a common-law public nuisance claim, the fourth cause of action asserts a claim for violation of Social Services Law § 145-b, and the fifth cause of action asserts a claim for fraud. The sixth cause of action is for unjust enrichment, and the seventh cause of action is for negligence.

The manufacturer defendants now jointly and separately move, pre-answer, for an order dismissing the complaint pursuant to CPLR 3211 (a) (1), (5), (7), and (8). While the court recognizes that subdivision (e) of CPLR 3211 permits a defendant to make only one motion under subdivision (a), it also recognizes the complexity of this matter as well as its unusual procedural framework; as the plaintiffs have been afforded ample opportunity to respond and have, in fact, submitted substantive opposition to each of the motions, the court will, for current purposes, waive compliance with the single-motion rule.

Before addressing the more comprehensive issues raised by the defendants, the court notes, insofar as certain of the manufacturer defendants seek dismissal on the ground that they are mere affiliates, the lack of evidence in the record to support any such claims, and the motions are denied to that extent without prejudice to any motions for summary judgment after joinder of issue.

When considering a motion to dismiss, a court must give the pleading a liberal construction, presume the allegations of the complaint are true, afford the plaintiff the benefit of every favorable inference, and determine only whether the facts as alleged fit within a cognizable legal theory (*EBC I, Inc. v Goldman, Sachs & Co.*, 5 NY3d 11, 19, 799 NYS2d 170 [2005]; *Leon v Martinez*, 84 NY2d 83, 87-88, 614 NYS2d 972 [1994]). “Whether a plaintiff can ultimately establish [the] allegations is not part of the calculus in determining a motion to dismiss” (*EBC I, Inc. v Goldman, Sachs & Co.*, 5 NY3d at 19, 799 NYS2d at 175).

Dismissal under CPLR 3211 (a) (1) may be granted only if the documentary evidence “utterly refutes plaintiff’s factual allegations” and conclusively establishes a defense to the asserted claim as a matter of law (*Goshen v Mutual Life Ins. Co.*, 98 NY2d 314, 326, 746 NYS2d 858 [2002]; *Leon v Martinez*, 84 NY2d at 88, 614 NYS2d at 972). A party seeking dismissal under CPLR 3211 (a) (5) based on the doctrine of res judicata must demonstrate that a final adjudication of a claim in a prior action between the parties on the merits by a court of competent jurisdiction precludes relitigation of that claim in the instant action (*Miller Mfg. Co. v Zeiler*, 45 NY2d 956, 958, 411 NYS2d 558 [1978]).

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Likewise, a defendant raising a statute of limitations defense under CPLR 3211 (a) (5) bears the initial burden of establishing a prima facie case that the time to commence the cause of action expired (see *Texeria v BAB Nuclear Radiology, P.C.*, 43 AD3d 403, 840 NYS2d 417 [2d Dept 2007]).

On a motion to dismiss under CPLR 3211 (a) (7), the initial test is whether the pleading states a cause of action, not whether the plaintiff has a cause of action (*Guggenheimer v Ginzburg*, 43 NY2d 268, 275, 401 NYS2d 182 [1977]; *Sokol v Leader*, 74 AD3d 1180, 904 NYS2d 153 [2d Dept 2010]). If documentary proof is submitted by a party seeking relief under CPLR 3211 (a) (7), the truthfulness of the pleadings need not be assumed. Instead, the test applied by the court is whether the plaintiff has a cause of action, not whether one is stated in the complaint (*Guggenheimer v Ginzburg*, 43 NY2d at 275, 401 NYS2d at 185; *Peter F. Gaito Architecture, LLC v Simone Dev. Corp.*, 46 AD3d 530, 530, 846 NYS2d 368, 369 [2d Dept 2007]; *Rappaport v International Playtex Corp.*, 43 AD2d 393, 395, 352 NYS2d 241, 243 [3d Dept 1974]).

If a defendant challenges the propriety or adequacy of service of a summons and complaint under CPLR 3211 (a) (8), it is the plaintiff's burden to prove, by a preponderance of the evidence, that jurisdiction over the defendant was obtained by proper service of process (e.g. *Aurora Loan Servs., LLC v Gaines*, 104 AD3d 885, 962 NYS2d 316 [2d Dept 2013]). The plaintiff, however, is not required to allege in the complaint the basis for personal jurisdiction (*Fishman v Pocono Ski Rental*, 82 AD2d 906, 440 NYS2d 700 [2d Dept 1981]), and to withstand a pre-answer motion to dismiss, the plaintiff need only demonstrate that facts "may exist" to support the exercise of jurisdiction over the defendant (CPLR 3211 [d]; *Peterson v Spartan Indus.*, 33 NY2d 463, 354 NYS2d 905 [1974]; *Ying Jun Chen v Lei Shi*, 19 AD3d 407, 796 NYS2d 126 [2d Dept 2005]).

In the analysis that follows, the court will first discuss those issues bearing on multiple causes of action before examining each of the causes of action separately for legal sufficiency.

Preemption

The manufacturer defendants contend that many of the plaintiffs' claims concerning alleged misrepresentations are not actionable under federal preemption principals. They seek dismissal of the plaintiffs' claims to the extent that they challenge such defendants' promotion of opioid medications consistent with Food and Drug Administration ("FDA") approved indications. Purdue also seeks dismissal on the ground that the plaintiffs' claims are preempted by federal law. Purdue argues that the plaintiffs wrongfully demand that it unilaterally change the FDA-approved uses for its prescription opioid medications. It also contends that the plaintiffs' claims would prohibit it from marketing opioids for their FDA-approved uses and indications, and would impose a duty upon the manufacturer defendants to alter the labels of their drugs in a manner that conflicts with their duties under federal law. The manufacturer defendants collectively insist that their marketing of opioids is consistent with FDA-approved labeling; therefore, any state law that would require them to make statements that are inconsistent with existing labeling, would directly conflict with the FDA regulations.

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The plaintiffs oppose the motion, arguing the United States Supreme Court has ruled that state tort claims do not stand as an obstacle to accomplishing the purposes of the Food, Drug, and Cosmetic Act (FDCA), 21 USC § 301 et seq., and FDA approval of a drug was not intended to displace state claims regarding the drug. The plaintiffs assert that despite FDA approval of the manufacturer defendants' opioid medications, such defendants were not required to repeat information they knew to be false in advertising and promoting their products after they became aware of new information that did not support their statements. The plaintiffs further assert that the manufacturer defendants failed to identify any federal obligations with which the plaintiffs' claims conflict, and that they ignore the plaintiffs' allegations that they engaged in off-label marketing and made representations designed to undermine information in drug labels.

The Supremacy Clause of the United States Constitution establishes that federal law "shall be the supreme Law of the Land" (US Const, art VI, cl 2). "A fundamental principle of the Constitution is that Congress has the power to preempt state law" through its enactments (*Crosby v National Foreign Trade Council*, 530 US 363, 372, 120 S Ct 2288, 2293 [2000]; see *Lee v Astoria Generating Co., L.P.*, 13 NY3d 382, 892 NYS2d 294 [2009]; see also *Doomes v Best Tr. Corp.*, 17 NY3d 594, 601, 935 NYS2d 268 [2011]; *Balbuena v IDR Realty LLC*, 6 NY3d 338, 812 NYS2d 416 [2006]). In certain instances, Congress may expressly preempt the state law; however, even where federal law does not contain an express preemption provision, state law must still yield to federal law to the extent of any conflict therewith (see *Warner v American Fluoride Corp.*, 204 AD2d 1, 616 NYS2d 534 [2d Dept 1994]). This doctrine of implied conflict preemption is generally found in two forms: impossibility preemption, which exists where "it is impossible for a private party to comply with both state and federal requirements," and obstacle preemption, which exists where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (*Doomes v Best Tr. Corp.*, 17 NY3d at 603, 935 NYS2d at 273 [internal quotation marks omitted]; see *Altria Group, Inc. v Good*, 555 US 70, 129 S Ct 538 [2008]; *City of New York v Job-Lot Pushcart*, 88 NY2d 163, 643 NYS2d 944 [1996]). In making a determination whether conflict preemption applies to bar a cause of action, the court must consider congressional intent, i.e., whether Congress intended to set aside the laws of a state to achieve its objectives (*Barnett Bank of Marion County, NA v Nelson*, 517 US 25, 30, 116 S Ct 1103, 1107 [1996]; *Louisiana Pub. Serv. Commn. v FCC*, 476 US 355, 369, 106 S Ct 1890, 1899 [1986]; *Lee v Astoria Generating Co., L.P.*, 13 NY3d at 391, 892 NYS2d at 299). The Supreme Court has "observed repeatedly that pre-emption is ordinarily not to be implied absent an actual conflict" (*English v General Elec. Co.*, 496 US 72, 90, 110 S Ct 2270, 2281 [1990]; see *Cipollone v Liggett Group, Inc.*, 505 US 504, 112 S Ct 2608 [1992]). "The mere fact of tension between federal and state law is generally not enough to establish an obstacle supporting preemption, particularly when the state law involves the exercise of traditional police power" (*Madeira v Affordable Hous. Found., Inc.*, 469 F3d 219, 241 [2d Cir 2006] [internal quotation marks omitted]).

It is well established that "the States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons" (*Medtronic, Inc. v Lohr*, 518 US 470, 475, 116 S Ct 2240, 2245 [1996]; see *Balbuena v IDR Realty LLC*, 6 NY3d 338, 812 NYS2d 416; *Madeira v Affordable Hous. Found., Inc.*, 469 F3d at 241). The protection of consumers against deceptive business practices is one area traditionally regulated by the

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states (*see California v ARC Am. Corp.*, 490 US 93, 109 S Ct 1661 [1989]). With regard to a conflict preemption analysis, the United States Supreme Court dictates that if Congress has legislated in a field traditionally occupied by the states, courts must “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress” (*id.* at 101, 109 S Ct at 1665; *Lee v Astoria Generating Co., L.P.*, 13 NY3d at 391, 892 NYS2d at 299). Therefore, a strong “presumption against preemption applies in consumer protection cases” (*In re Ford Fusion & C-Max Fuel Econ. Litig.*, 2015 WL 7018369, *25 [SD NY 2015]).

Here, the question before the court is whether New York’s consumer protection laws and traditional tort principals pose an obstacle to the FDA’s regulation of prescription drug promotion and advertising or make it impossible for the manufacturer defendants herein to comply with those regulations as a matter of law. “The party arguing that federal law preempts a state law bears the burden of establishing preemption” (*id.* at *23).

In the 1930s, because of increased concern about the availability of unsafe drugs and fraudulent marketing of drugs, Congress enacted the FDCA, which authorized the FDA, among other things, to regulate the prescription drug industry (*Wyeth v Levine*, 555 US 555, 567, 129 S Ct 1187, 1196 [2009]; *Medtronic, Inc. v Lohr*, 518 US at 475, 116 S Ct at 2246; *Dobbs v Wyeth Pharm.*, 797 F Supp 2d 1264, 1270 [WD Okla 2011]). The legislation “enlarged the FDA’s powers to protect the public health and assure the safety, effectiveness, and reliability of drugs” (*Wyeth v Levine*, 555 US at 567, 129 S Ct at 1195-1196). It required manufacturers to submit a new drug application—including proposed labeling—to the FDA for review prior to distribution of the drug, and the FDA could reject the application if it determined that the drug was not safe for use as labeled (*id.*). Under the FDCA, a drug’s labeling is construed broadly, and includes “any article that supplements or explains the product even if the article is not physically attached to it” (*Sandoval v PharmaCare US, Inc.*, 2018 WL 1633011, *2 [9th Cir 2018] [internal quotation marks omitted]; *see* 21 USC § 321 [m]). Labeling also includes descriptions of a drug in brochures and through media, and references published for use by medical practitioners, which contain drug information supplied by the manufacturer, packer, or distributor of the drug (21 CFR § 202.1 [I] [2]). Thus, in many respects, opioid medication marketing and advertising materials perform the function of labeling (*see Kordel v United States*, 335 US 345, 350, 69 S Ct 106, 110 [1948]; *Sandoval v PharmaCare US, Inc.*, 2018 WL 1633011). The FDA, however, generally does not review unbranded promotional materials, i.e., materials that promote the use of a type of drug but do not identify any particular drug by name (*see City of Chicago v Purdue Pharma L.P.*, 2015 WL 2208423, *2 [ND Ill 2015]).

FDA regulation provides that a manufacturer must seek approval from the FDA prior to making any change to its drug labeling by submitting a supplemental application for review; however, the FDA permits pre-approved changes by the manufacturer under certain circumstances (21 CFR § 314.70 [c]; *Wyeth v Levine*, 555 US at 567, 129 S Ct at 1189; *Dobbs v Wyeth Pharm.*, 797 F Supp at 1270). Pursuant to the “changes being effected” (CBE) regulation, a manufacturer is permitted to make a label change where the change is needed “to add or strengthen a contraindication, warning, [or] precaution . . . or to add or strengthen an instruction about dosage and administration that is intended to increase the

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safe use of the drug product” (*PLIVA, Inc. v Mensing*, 564 US 604, 614, 131 S Ct 2567, 2575 [2011] [internal quotation marks omitted]; *Dobbs v Wyeth Pharm.*, 797 F Supp at 1270). In the spirit of the FDCA to promote the safety, effectiveness, and reliability of drugs, Congress made it clear that despite FDA oversight, manufacturers were “responsible for updating their labels” at all times (*Wyeth v Levine*, 555 US at 567, 129 S Ct at 1195-1196; see *Sullivan v Aventis, Inc.*, 2015 WL 4879112 [SD NY 2015]). “[T]he manufacturer is charged ‘both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market’ ” (*Utts v Bristol-Myers Squibb Co.*, 251 F Supp 3d 644, 659 [SD NY 2017], quoting *Wyeth v Levine*, 555 US at 571, 129 S Ct at 1197). Notwithstanding those obligations, if a manufacturer can show clear evidence that the FDA would not have approved a labeling change, the CBE exception does not apply (*id.*). Additionally, labeling changes pursuant to the CBE regulation may only be made on the basis of “newly acquired information” (*Utts v Bristol-Myers Squibb Co.*, 226 F Supp 3d 166, 177 [SD NY 2016]; see 21 CFR § 314.70 [c] [6] [iii]). If a claim against a manufacturer “addresses newly acquired information and addresses a design or labeling change that a manufacturer may unilaterally make without FDA approval, then there may be no preemption of the state law claim” (*id.* at 182; see *Wyeth v Levine*, 555 US 569, 129 S Ct 1197; *Utts v Bristol-Myers Squibb Co.*, 251 F Supp 3d 644).

The manufacturer defendants challenge the plaintiffs’ claims on the ground that the plaintiffs seek to require such defendants to change the FDA-approved indications for their opioid medications. The manufacturer defendants assert that central to the plaintiffs’ complaint are the allegations that such defendants fraudulently and improperly promoted opioids to treat chronic pain, and that such defendants failed to disclose that there was no evidence to support the long-term use of opioids. They contend that the plaintiffs’ allegations go against the findings of the FDA, and that the FDA did not require them to make such disclosures. The manufacturer defendants further argue that the plaintiffs cannot show the existence of newly acquired information that would have required them to make unilateral changes to their product labeling.

There is no dispute that in the late 1980s and early 1990s, the FDA approved the prescription opioid medications at issue to treat chronic pain. FDA-approved labeling for these medications warned medical professionals and consumers about some of the risks associated with opioid use, and drug manufacturers provided educational materials to medical professionals on treatment guidelines. Nevertheless, the FDA’s approval of opioids for consumption by the general public does not mean that states, and specifically, the plaintiffs herein, may not seek to protect their residents from the unlawful activities of defendants concerning those drugs (see *Yugler v Pharmacia & Upjohn Co.*, 2001 WL 36387743 [Sup Ct, NY County 2001]; see generally *English v General Elec. Co.*, 496 US 72, 87, 110 S Ct 2270 [1990] [“the mere existence of a federal regulatory or enforcement scheme . . . does not by itself imply pre-emption of state remedies”]). “[M]anufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly” (*Wyeth v Levine*, 555 US at 578-579, 129 S Ct at 1202).

On the face of the complaint, it does not appear that the plaintiffs seek to compel the manufacturer defendants to stop selling their medications (see *Mutual Pharm. Co. v Bartlett*, 570 US

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472, 133 S Ct 2466 [2013]), nor do the plaintiffs seek to challenge the FDA's approval of their products (see *Buckman Co. v Plaintiffs' Legal Comm.*, 531 US 341, 121 S Ct 1012 [2001]; *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F3d 34, 36 [1st Cir 2015]) or to enforce FDA regulations (see *PDK Labs, Inc. v Friedlander*, 103 F3d 1105 [2d Cir 1997]; *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1836443, *7 [ND Ill 2017]). The plaintiffs claim that the manufacturer defendants' business practices in promoting, advertising, and marketing their FDA-approved opioids have run afoul of New York law and traditional tort principals, and that they should be held liable.

The plaintiffs allege that when promoting prescription opioids, the manufacturer defendants made representations that were not supported by scientific studies, thus preventing clinicians and consumers from making informed decisions about whether to prescribe or to use opioids as a primary form of chronic pain treatment, that they used marketing strategies to evade consumer protection laws, and that they used front groups or third parties to promote opioids as superior pain relief medication through unbranded materials. The plaintiffs do not demand that the manufacturer defendants remove their products from the market as the defendants seem to suggest. Instead, the plaintiffs' claims are predicated "on a more general obligation—the duty not to deceive" their residents (*Cipollone v Liggett Group, Inc.*, 505 US 504, 528-529, 112 S Ct 2608, 2624 [1992]; see *In re Ford Fusion & C-Max Fuel Econ. Litig.*, 2015 WL 7018369). As previously indicated, FDA approval of drug labeling does not necessarily mean that the FDA has authorized the manufacturer's marketing practices (see generally *Kramer v Bausch & Lomb, Inc.*, 264 AD2d 596, 695 NYS2d 553 [1st Dept 1999]; *City of Chicago v Purdue Pharma L.P.*, 2015 WL 2208423, *2 [ND Ill 2015]). The manufacturer defendants have failed to show that the FDA has approved their means, methods, and/or the content of their drug promotion to warrant a finding that the plaintiffs' claims are preempted by virtue of the FDA's approval of their drug.

With respect to information contained in the manufacturer defendants' drug labels, particularly concerning addiction and the long-term use of opioids, it is certainly a closer call whether preemption applies. The court finds that the plaintiffs' claims are not preempted under the circumstances.

There are two stages to the preemption inquiry before the court. The plaintiffs herein must show that newly acquired information exists such that the manufacturer could unilaterally change its label in accordance with the CBE regulation, and if the plaintiff can prove the existence of newly acquired information, "the manufacturer may [] establish an impossibility preemption defense by presenting clear evidence that the FDA would have exercised its authority to reject the labeling change" (*Utts v Bristol-Myers Squibb Co.*, 251 F Supp 3d 644, 672 [internal quotation marks omitted]). The plaintiffs allege that the manufacturer defendants acquired new information concerning addiction and the long-term use of opioids, which, if acted upon, would have strengthened instruction about dosing and administration of the drugs, yet defendants continued to market their products without disclosing such information to consumers or marketed their drugs by making statements that were contrary to the newly acquired information (see *Wyeth v Levine*, 555 US at 578-579, 129 S Ct at 1202; cf. *Utts v Bristol-Myers Squibb Co.*, 251 F Supp 3d 644, 672). The plaintiffs cite many studies that were conducted subsequent to the FDA's approval of the medications—studies that the manufacturer defendants allegedly knew about—which contradict such defendants' promotional statements and

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materials. The plaintiffs also allege numerous instances where the manufacturer defendants suppressed or indirectly attempted to suppress information about the effects of their drugs that was contrary to their promotional statements. The court finds that at this stage of the proceedings the plaintiffs have satisfied their pleading burden with regard to newly acquired information (*see* CPLR 3211).

The manufacturer defendants further argue that the FDA has addressed the claims that plaintiffs now advance, and their marketing is consistent with FDA-approved labeling; therefore, preemption applies. In July 2012, Physicians for Responsible Opioid Prescribing (PROP), a coalition of concerned doctors, filed a citizen petition requesting that the FDA change some indications for opioid medications. PROP stated that clinicians were under the false impression that chronic opioid therapy was an evidence-based treatment for non-cancer pain, and asked the FDA to prohibit manufacturers from marketing opioids for conditions for which the use of opioids had not been proven safe and effective. In 2013, the FDA responded to the petition, granting it in part and rejecting it in part. Recognizing the grave risks associated with opioid use, the FDA required opioid manufacturers to include in their drug labels a warning that opioids should be used only when alternative treatments were inadequate. The FDA declined to recommend a daily maximum dose or the maximum duration of opioid treatment, and stated that more controlled studies were needed concerning long-term use of opioids. The agency acknowledged that high rates of addiction were concerning, and it ordered opioid manufacturers to conduct post-approval studies on the long-term use of the medications.

In *Wyeth*, the United States Supreme Court articulated that “absent clear evidence that the FDA would not have approved a change to [the drug’s] label” a court cannot conclude that it was impossible for the drug manufacturer to comply with both federal and state requirements (*Wyeth v Levine*, 555 US at 571, 129 S Ct at 1198). Citing *Cerveny v Aventis, Inc.* (855 F3d 1091, 1105 [10th Cir 2017]), the manufacturer defendants argue that the FDA’s rejection of the PROP citizen petition constitutes “clear evidence” that the FDA would have rejected a labeling change concerning the long-term use of opioids, the concept of pseudoaddiction (a preoccupation with achieving adequate pain relief that leads to higher consumption levels of opioids), and addiction withdrawal. By way of background, in *Cerveny*, the Tenth Circuit held that the FDA’s rejection of a citizen petition, which made “arguments virtually identical” to the plaintiffs’ claims, was clear evidence that the FDA would have rejected the plaintiffs’ proposed change to a drug label (*Cerveny v Aventis, Inc.*, 855 F3d at 1105). The plaintiffs in that case admitted that their claims were “based on the same theories and scientific evidence presented in [the] citizen petition” (*id.* at 1101).

“[W]hen considering a preemption argument in the context of a motion to dismiss, the factual allegations relevant to preemption must be viewed in the light most favorable to the plaintiff. A [] court may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted” (*Utts v Bristol-Myers Squibb Co.*, 251 F Supp 3d at 672 [internal quotation marks omitted]). The plaintiffs in this action allege that the manufacturer defendants made presentations to medical professionals and others about the efficacies of long-term use of opioids as though those statements were supported by substantial evidence. However, the manufacturer defendants acknowledge that the FDA found that there was an absence of well-controlled studies of opioid use longer than 12 weeks. The plaintiffs also allege that the manufacturer defendants knew about the addictive effects of

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opioids many years before the FDA's 2013 response to the PROP petition, but minimized those effects when promoting, marketing, and advertising the drugs. For example, the plaintiffs allege that the manufacturer defendants used the concept of pseudoaddiction as an excuse to encourage medical professionals to prescribe more or higher doses of opioids despite knowledge of the high risk of abuse. The manufacturer defendants allegedly distributed treatment guidelines to professionals, which indicated that a clinicians' first response to treating pseudoaddiction was to increase dosing although other adequate treatment options were available. Additionally, unlike the plaintiffs in *Cerveny*, the plaintiffs' allegations here are not based upon the same theories and scientific evidence presented in the PROP petition (see *Cerveny v Aventis, Inc.*, 855 F3d at 1101). The plaintiffs herein make allegations concerning the defendants' business practices.

Moreover, the court concludes that, under the circumstances, the FDA's "less-than-definitive determination" concerning PROP's request for maximum dosage and treatment duration does not meet the *Wyeth* standard of clear evidence (see *Amos v Biogen Idec Inc.*, 249 F Supp 3d 690, 699 [WD NY 2017] ["the Court compares the evidence presented with the evidence in *Wyeth*, to determine whether it is more or less compelling"]). In its response to PROP, the FDA stated that the petitioners did not present sufficient evidence to support their recommendations concerning the long-term use of opioids. However, in light of the concerning high rates of addiction, the FDA requested "further exploration" of the issues. Inasmuch as "manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge" this court cannot conclude as a matter of law that the agency would have rejected proposals from the drug manufacturers to change their labeling, which in effect would have strengthened dosing instruction and administration of the drugs (*Wyeth v Levine*, 555 US at 578-579, 129 S Ct at 1202; *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1836443, *7). Accordingly, the court finds that the plaintiffs' state-law claims do not make it impossible for the manufacturer defendants to comply with the FDA's regulations; therefore, the manufacturer defendants' application to dismiss those claims on federal preemption grounds is denied (see CPLR 3211 [a] [7]; *Wyeth v Levine*, 555 US 555, 129 S Ct 1187; *Sullivan v Aventis, Inc.*, 2015 WL 4879112; see generally *Feinberg v Colgate Palmolive Co.*, 34 Misc 3d 1243[A], 950 NYS2d 608 [Sup Ct, NY County 2012]).

Municipal Cost Recovery Rule

The manufacturer defendants' argument that the complaint does not allege a cognizable injury, i.e., that the plaintiffs are barred under the municipal cost recovery rule from recovering the costs of governmental services incurred in connection with the opioid crisis, is rejected. The municipal cost recovery rule, also known as the free public services doctrine, precludes municipalities from recovering as damages from a tortfeasor the cost of public services, such as police and fire protection, required as a consequence of an accident or emergency (see *Koch v Consolidated Edison Co. of N.Y.*, 62 NY2d 548, 560, 479 NYS2d 163 [1984]; *Austin v City of Buffalo*, 182 AD2d 1143, 586 NYS2d 841 [4th Dept 1992]; *City of Buffalo v Wilson*, 179 AD2d 1079, 580 NYS2d 679 [4th Dept 1992]; see also e.g. *County of Erie, New York v Colgan Air, Inc.*, 711 F3d 147 [2d Cir 2013]; *City of Flagstaff v Atchison, Topeka & Santa Fe Ry. Co.*, 719 F2d 322 [9th Cir 1983]). In *Koch*, the Court of Appeals held that New York City could not recover as damages from Consolidated Edison the costs it incurred "for wages,

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salaries, overtime and other benefits of police, fire, sanitation and hospital personnel from whom services (in addition to those which would normally have been rendered) were required” as a consequence of a 25-hour blackout caused by the company’s gross negligence, holding “[t]he general rule is that public expenditures made in the performance of governmental functions are not recoverable” (*Koch v Consolidated Edison Co. of N.Y.*, 62 NY2d at 560, 479 NYS2d at 170). And in *City of Flagstaff*, a seminal case for the municipal cost recovery rule, the Court of Appeals held that the cost of providing police, fire and emergency services “from fire or safety hazards is to be borne by the public as a whole, not assessed against the tortfeasor whose negligence creates the need for the services,” reasoning that a rule allocating such expenses to the tortfeasor who caused an accident or other public emergency would upset “[e]xpectations of individuals and businesses, as well as their insurers,” and that the legislature, not the court, is the appropriate forum in which to address whether the costs related to public emergencies should be shifted to the responsible party (*City of Flagstaff v Atchison, Topeka & Santa Fe Ry. Co.*, 917 F2d at 323-324). The municipal cost recovery rule, however, does not bar a cause of action for public nuisance (*see County of Erie, New York v Colgan Air, Inc.*, 711 F3d 147; *see also State of New York v Schenectady Chems.*, 117 Misc 2d 960, 459 NYS2d 971 [Sup Ct, Rensselaer County 1983]), and an exception exists permitting recovery for public expenses authorized by statute or regulation (*Koch v Consolidated Edison Co. of N.Y.*, 62 NY2d at 561, 479 NYS2d at 170).

Here, the plaintiffs allege, among other things, they were harmed by having to pay the costs of prescription opioid therapy for employees and Medicaid beneficiaries complaining of chronic, non-cancer pain when such treatment was not medically necessary or reasonably required, and that, but for the misrepresentations made by the manufacturer defendants about the benefits and risks of long-term prescription opioid therapy, they would not have approved payment for such therapy. Moreover, a review of the current state of the law revealed no case law supporting the manufacturer defendants’ contention that such rule bars recovery for municipal expenses incurred, not by reason of an accident or an emergency situation necessitating “the normal provision of police, fire and emergency services” (*City of Flagstaff v Atchison, Topeka & Santa Fe Ry. Co.*, 719 F2d at 324), but to remedy public harm caused by an intentional, persistent course of deceptive conduct. The manufacturer defendants’ argument that, despite allegations they designed and implemented materially deceptive marketing campaigns to mislead the public and prescribers about the risks and benefits of prescription opioids, the municipal cost recovery rule forecloses the plaintiffs from recovering the costs for services to treat residents suffering from prescription opioid abuse, addiction or overdose, or for the increased costs of programs implemented to stem prescription opioid-related criminal activities, if accepted, would distort the doctrine beyond recognition.

Statute of Limitations

The manufacturer defendants also jointly contend that all of the plaintiffs’ causes of action must be dismissed to the extent that they are predicated upon acts or omissions occurring outside the relevant limitations period, i.e., six years for the causes of action based in common-law fraud and unjust enrichment, and three years for the remaining causes of action. The manufacturer defendants further contend that the plaintiffs cannot rely on the two-year discovery period for assertion of a cause of action in fraud, because the allegations in the complaint confirm that they could have discovered the alleged

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fraud from information publicly available well before August 31, 2014, and because the plaintiffs cannot demonstrate that they were unable to discover information pertaining to the prescriptions underlying their claims prior to that date.

Cephalon separately contends that, even if the six-year limitations period applied to all of the plaintiffs' claims, the plaintiffs failed to allege a single fraudulent act or omission on its part occurring after August 2010. Moreover, as the plaintiffs acknowledge that the false statements which they attribute to Cephalon were "available nationally" and "cited widely," and that the risks associated with opioids were clear as early as the 1970s and 1980s, the plaintiffs cannot rely on the two-year discovery period for assertion of a cause of action in fraud.

Purdue separately contends that OxyContin has only been sold in its current "reformulated," "abuse-deterrent" form since 2010—more than six years prior to the commencement of this action—and that the majority of statements attributed to it in the complaint are either undated or were made well outside the six-year statute of limitations.

Actavis separately contends that there are but a scant few paragraphs in the complaint containing allegations that plausibly fit within either of relevant three- or six-year limitations periods, and that even those allegations amount to little more than general observations describing lawful conduct, e.g., what Actavis spent on advertising.

The plaintiffs counter that their causes of action are timely, whether because they did not accrue until the plaintiffs either suffered injury or discovered the wrong, or by application of the "continuing wrong" doctrine, which serves to toll the running of a period of limitations to the date on which the last wrongful act is committed, or because the facts alleged in the complaint serve to toll the statute of limitations based on fraudulent concealment. As to Cephalon, the plaintiffs contend that the complaint does, in fact, allege statements made by or attributable to Cephalon that were made after 2010; additionally, to the extent the complaint alleges misrepresentations in written publications, the plaintiffs claim the date that those statements were first published is not determinative for statute of limitations purposes, as those materials continued to circulate and be relied on long after they were initially introduced. As to Purdue, the plaintiffs note that not all of their allegations relating to that manufacturer pertain to OxyContin. According to the plaintiffs, not only did Purdue deceptively promote its branded opioids but, through its direct marketing and unbranded materials, it also misrepresented the benefits and dangers of opioids generally.

"To dismiss a cause of action pursuant to CPLR 3211 (a) (5) on the ground that it is barred by the statute of limitations, a defendant bears the initial burden of establishing prima facie that the time in which to sue has expired. Only if such prima facie showing is made will the burden then shift to the plaintiff to aver evidentiary facts establishing that the case falls within an exception to the statute of limitations. In order to make a prima facie showing, the defendant must establish, inter alia, when the plaintiff's cause of action accrued" (*Swift v New York Med. Coll.*, 25 AD3d 686, 687, 808 NYS2d 731, 732-733 [2d Dept 2006] [internal citations and quotation marks omitted]; accord *Pace v Raisman & Assoc., Esqs., LLP*, 95 AD3d 1185, 945 NYS2d 118 [2d Dept 2012]).

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“In general, a cause of action accrues, triggering commencement of the limitations period, when all of the factual circumstances necessary to establish a right of action have occurred, so that the plaintiff would be entitled to relief” (*Gaidon v Guardian Life Ins. Co. of Am.*, 96 NY2d 201, 210, 727 NYS2d 30, 35 [2001]). While a claim for breach of contract accrues on the date of the breach, irrespective of the plaintiff’s awareness of the breach (*Ely-Cruikshank Co. v Bank of Montreal*, 81 NY2d 399, 599 NYS2d 501 [1993]), a tort claim accrues only when it becomes enforceable, that is, when all the elements of the tort can be truthfully alleged in the complaint (*Kronos, Inc. v AVX Corp.*, 81 NY2d 90, 595 NYS2d 931 [1993]). When damage is an essential element of the tort, the claim is not enforceable until damages are sustained (*Kronos, Inc. v AVX Corp.*, 81 NY2d 90, 595 NYS2d 931). In an action to recover for a liability created or imposed by statute, the statutory language determines the elements of the claim which must exist before the action accrues (*Matter of Motor Veh. Acc. Indem. Corp. v Aetna Cas. & Sur. Co.*, 89 NY2d 214, 652 NYS2d 584 [1996]).

Here, it is evident that injury is an essential element of no fewer than four of the causes of action pleaded. To state a cause of action for deceptive acts and practices under General Business Law § 349, the plaintiffs were required to allege that the defendants engaged in consumer-oriented acts or practices that are “deceptive or misleading in a material way and that plaintiff has been injured by reason thereof” (*Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 25, 623 NYS2d 529, 532 [1995]). Similarly, a cause of action for false advertising pursuant to General Business Law § 350 is stated so long as it is pleaded that “the advertisement (1) had an impact on consumers at large, (2) was deceptive or misleading in a material way, and (3) resulted in injury” (*Andre Strishak & Assoc. v Hewlett Packard Co.*, 300 AD2d 608, 609, 752 NYS2d 400, 403 [2d Dept 2002]). The elements of a cause of action sounding in fraud are a material misrepresentation of an existing fact, made with knowledge of the falsity, an intent to induce reliance thereon, justifiable reliance upon the misrepresentation, and damages (*Introna v Huntington Learning Ctrs.*, 78 AD3d 896, 911 NYS2d 442 [2d Dept 2010]); thus, a cause of action for fraud cannot accrue until every element of the claim, including injury, can truthfully be alleged (*Carbon Capital Mgt., LLC v American Express Co.*, 88 AD3d 933, 932 NYS2d 488 [2d Dept 2011]). And a cause of action sounding in negligence likewise accrues as soon as the claim becomes enforceable, that is, on the earliest date upon which the claimed negligence causes a plaintiff to sustain damages (*see Brooks v AXA Advisors*, 104 AD3d 1178, 961 NYS2d 648 [4th Dept], *lv denied* 21 NY3d 858, 970 NYS2d 748 [2013]).

As to those causes of action, the manufacturer defendants have not identified any relevant date of injury but, rather, contend only that the acts and omissions on which they are based did not take place within the applicable limitations periods. Consequently, as it has not been established when any of those causes of action accrued, it cannot be said at this juncture that any of them is untimely—except to note, even assuming the applicability of the “continuing wrong” doctrine (*see generally Affordable Hous. Assoc., Inc. v Town of Brookhaven*, 150 AD3d 800, 54 NYS3d 122 [2d Dept 2017]), that the plaintiffs may recover monetary damages only to the extent that they were sustained within the applicable limitations period immediately preceding the commencement of this action (*see State of New York v Schenectady Chems.*, 103 AD2d 33, 479 NYS2d 1010 [3d Dept 1984]; *Kearney v Atlantic Cement Co.*, 33 AD2d 848, 306 NYS2d 45 [3d Dept 1969]). And while some recovery of damages may be time-barred, dismissal—even partial dismissal—is not appropriate at this juncture, as the court is not yet able to

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determine the precise nature and timing of the plaintiffs' respective claims (*see Airco Alloys Div. v Niagara Mohawk Power Corp.*, 76 AD2d 68, 430 NYS2d 179 [4th Dept 1980]).

The manufacturer defendants have likewise failed to show that the cause of action alleging public nuisance is untimely. The rule with respect to nuisance or other continuing wrongs is that the action accrues anew on each day of the wrong, so that the right to maintain the cause of action continues as long as the nuisance exists (*Airco Alloys Div. v Niagara Mohawk Power Corp.*, 76 AD2d 68, 430 NYS2d 179; 17A Carmody-Wait 2d § 107:95). Here, the plaintiffs have alleged a continuing wrong, perpetrated by all the defendants, involving deceptive marketing practices that began over a decade ago and that have continued up to the time of commencement of this action. That such a nuisance may have existed for more than three years, then, does not bar the cause of action; as before, however, the court notes that damages are recoverable only to the extent they were sustained during the three years prior to the commencement of the action (CPLR 214; *State of New York v Schenectady Chems.*, 103 AD2d 33, 479 NYS2d 1010; *Kearney v Atlantic Cement Co.*, 33 AD2d 848, 306 NYS2d 45).

As to the cause of action pleaded under Social Services Law § 145-b, the analysis differs but the result is essentially the same. First, as to the applicable limitations period, the court notes that although fraud is a component of Social Services Law § 145-b, the remedy contemplated by the statute is at once broader and narrower than that in fraud; it serves not only to create a right on behalf of local social services districts and the State to sue for damages in cases of fraud and misrepresentation in connection with Medicaid reimbursement but also to provide a financial deterrent in the form of treble damages in order to curb such abuses (Legislative Mem, McKinney's Session Laws of NY at 1686-1687). Since this remedy did not exist at common law, the three-year statute of limitations for statutory causes of action applies (CPLR 214 [2]; *see Gaidon v Guardian Life Ins. Co. of Am.*, 96 NY2d 201, 727 NYS2d 30). Second, as to date of accrual, it is clear that in an action to recover for a liability created or imposed by statute, the statutory language determines the elements of the claim which must exist before the action accrues (*Matter of Motor Veh. Acc. Indem. Corp. v Aetna Cas. & Sur. Co.*, 89 NY2d 214, 652 NYS2d 584). Since it is unlawful under Social Services Law § 145-b even to attempt to obtain Medicaid reimbursement by fraudulent means, it is conceivable that a violation of the statute may occur without a plaintiff having sustained actual damages, in which case the statute provides for civil damages in the amount of \$5,000.00. Thus, damages is not an element of the cause of action, and the manufacturer defendants are correct in asserting both that the three-year limitations period began to run upon the occurrence of the alleged misconduct, and that the plaintiffs may not recover damages based on alleged acts or omissions occurring more than three years prior to the commencement of this action. Since it is pleaded, however, that the fraudulent conduct underlying the cause of action continued up to the time that this action was commenced, and the manufacturer defendants having failed to demonstrate an earlier accrual date, the court will not dismiss it as time-barred.

Nor has it been demonstrated that the cause of action sounding in unjust enrichment is untimely. The plaintiffs allege, in relevant part, that the manufacturer defendants, as an expected and intended result of deceptive conduct intended to mislead the plaintiffs as to the risks and benefits of opioid use and encourage the plaintiffs to pay for long-term opioid prescriptions, were enriched from opioid purchases made by the plaintiffs and that it would be unjust and inequitable to permit them to enrich

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themselves at the plaintiffs' expense. While there is no limitations period identified in the CPLR within which to bring a claim for unjust enrichment, it is recognized that the three-year statute of limitations governs where, as here, the claim arises from tortious conduct and monetary relief is sought (*DiMatteo v Cosentino*, 71 AD3d 1430, 896 NYS2d 778 [4th Dept 2010]; *Ingrami v Rovner*, 45 AD3d 806, 847 NYS2d 132 [2d Dept 2007]; *Lambert v Sklar*, 30 AD3d 564, 817 NYS2d 378 [2d Dept 2006]). It is also recognized that the claim accrues "upon the occurrence of the wrongful act giving rise to the duty of restitution" (*Ingrami v Rovner*, 45 AD3d at 808, 847 NYS2d at 134). Here, as it is alleged that the wrongful conduct has continued through the time of commencement of this action, the statute of limitations does not operate as a complete defense to the cause of action as pleaded; as noted previously, however, damages may be recovered only to the extent the claim is based on conduct occurring within the three years prior to the commencement of this action.

In so ruling, the court does not reach the question of whether any cause of action is subject to either the discovery rule for actions based on fraud (CPLR 203 [g]; 213 [8]) or the doctrine of equitable estoppel.

Res Judicata

Endo's argument pursuant to CPLR 3211 (a) (5), that the plaintiffs' claims against it are barred by an assurance of discontinuance executed in March 2016 concerning its marketing of Opana ER, its branded version of the semi-synthetic, opioid analgesic oxycodone, is rejected. It is fundamental that a final adjudication of a claim on the merits by a court of competent jurisdiction "is conclusive of the issues of fact and questions of law necessarily decided therein" and precludes relitigation of that claim by the parties and those in privity with them (*Gramatan Home Invs. Corp. v Lopez*, 46 NY2d 481, 485, 414 NYS2d 308, 311 [1979]; see *Parker v Blauvelt Volunteer Fire Co.*, 93 NY2d 343, 690 NYS2d 478 [1999]; *Matter of Hodes v Axelrod*, 70 NY2d 364, 520 NYS2d 933 [1987]). The doctrine of res judicata operates to preclude litigation of all other claims arising out of the same transaction or series of transactions that could have or should have been raised in the prior proceeding, even if such claims are based on different theories or seek a different remedy (see *O'Brien v City of Syracuse*, 54 NY2d 353, 445 NYS2d 687 [1981]; *Smith v Russell Sage Coll.*, 54 NY2d 185, 445 NYS2d 68 [1981]; *Lasky v City of New York*, 281 AD2d 598, 722 NYS2d 391 [2d Dept 2001]). Collateral estoppel, a corollary to the doctrine of res judicata, "precludes a party from relitigating in a subsequent action or proceeding an issue clearly raised in a prior action or proceeding and decided against that party or those in privity, whether or not the tribunals or causes of action are the same" (*Ryan v New York Tel. Co.*, 62 NY2d 494, 500, 478 NYS2d 823, 826 [1984]). A party seeking to invoke the benefit of the collateral estoppel doctrine must demonstrate that the identical issue necessarily was decided in the prior action against the opposing party, or one in privity with such party, and is decisive of the present action (*Buechel v Bain*, 97 NY2d 295, 303-304, 740 NYS2d 252, 257 [2001]; see *D'Arata v New York Cent. Mut. Fire Ins. Co.*, 76 NY2d 659, 563 NYS2d 24 [1990]; *Kaufman v Eli Lilly & Co.*, 65 NY2d 449, 492 NYS2d 584 [1985]; *David v State of New York*, 157 AD3d 764, 69 NYS3d 110 [2d Dept 2018]). It is noted that, except in rare circumstances, the defense of estoppel may not be invoked against the state or its political subdivisions to prevent a governmental body from enforcing the law or discharging its duties as a matter

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of policy (*Matter of E.F.S. Ventures Corp. v Foster*, 71 NY2d 359, 370, 526 NYS2d 56, 61 [1988]; *Matter of Hamptons Hosp. & Med. Ctr. v Moore*, 52 NY2d 88, 95, 436 NYS2d 239, 242 [1981]).

Further, Executive Law § 63 (12) authorizes the Attorney General to seek injunctive relief, restitution, and damages for repeated or persistent fraudulent or illegal acts in conducting business activities in New York. The Attorney General, however, may forgo litigation when a violation of a state law is discovered and instead enter into an “assurance of discontinuance of any act or practice in violation of such law” (Executive Law § 63 [15]).

It is undisputed that the Attorney General commenced an investigation in 2013 into Endo’s marketing of Opana ER in New York. Years later, after obtaining documentary and testimonial evidence from Endo, the Attorney General determined that certain “practices, statements and omissions” by Endo and its employees in connection with the marketing of Opana ER, collectively referred to as the “covered conduct,” violated General Business Law §§ 349 and 350 and Executive Law § 63 (12). The Attorney General, in an exercise of his discretion, decided to enter into an assurance of discontinuance with Endo in lieu of civil litigation. In March 2016, Endo and the Attorney General executed the assurance of discontinuance, wherein Endo agreed, among other things, not to make certain statements regarding the addictiveness of Opana ER or opioids, to provide “truthful and balanced summaries of the results of all Endo-sponsored studies regarding the purported tamper-resistant feature of Reformulated Opana ER,” to require all authors of articles concerning Endo-sponsored studies to disclose any financial relationships with Endo, and to “maintain and enhance its program consisting of internal procedures designed to identify potential abuse, diversion or inappropriate prescribing of opioids.” Endo also agreed to pay \$200,000 as penalties, fees, and costs, and to submit to monitoring by the Office of the Attorney General. In addition, the assurance states that “[n]othing contained herein shall be construed to deprive any member or other person or entity of any private right under law or equity,” and that it does not limit in any way the Attorney General’s power to take actions against Endo for either noncompliance with its terms or noncompliance with any applicable law as to “with respect to any matters that are not part of the covered conduct.” Significantly, Endo neither admitted nor denied the Attorney General’s various findings of unlawful “practices, statements and omissions” under General Business Law §§ 349 and 350 regarding the marketing of Opana ER.

Contrary to the assertions by Endo’s counsel, the March 2016 assurance of discontinuance does not constitute a stipulation of settlement that is binding on the plaintiffs. The settlement of an action prior to the entry of judgment operates to finalize the action without regard to the validity of the original claim, “and the action [is] accordingly considered, in contemplation of law, as if it had never begun” (*Peterson v Forkey*, 50 AD2d 774, 775, 376 NYS2d 560, 561-562 [1st Dept 1975]; see *Ott v Barash*, 109 AD2d 254, 491 NYS2d 661 [2d Dept 1985]; see generally *Yonkers Fur Dressing Co. v Royal Ins. Co.*, 247 NY 435 [1928]). When an action is discontinued, “it is as if it had never been; everything done in the action is annulled and all prior orders in the case are nullified” (*Newman v Newman*, 245 AD2d 353, 354, 665 NYS2d 423, 424 [2d Dept 1997]). By contrast, “a stipulation of discontinuance with prejudice without reservation of right or limitation of the claims disposed of is entitled to preclusive effect under the doctrine of res judicata” (*Liberty Assoc. v Etkin*, 69 AD3d 681, 682-683, 893 NYS2d 564, 565 [2d Dept 2010]), and bars future actions between the same parties or those in privity with them

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(*Matter of Chiantella v Vishnick*, 84 AD3d 797, 798, 922 NYS2d 525, 527 [2d Dept 2011]; *Abraham v Hermitage Ins. Co.*, 47 AD3d 855, 855, 851 NYS2d 608, 609 [2d Dept 2008]; *Matter of State of New York v Seaport Manor A.C.F.*, 19 AD3d 609, 610, 797 NYS2d 538, 539 [2d Dept 2005]). Generally, to establish privity with a party to a prior action, “the connection . . . must be such that the interests of the nonparty can be said to have been represented in the prior proceeding” (*Green v Santa Fe Indus.*, 70 NY2d 244, 253, 519 NYS2d 793, 796 [1987]). As explained by the Court of Appeals, “those who are successors to a property interest, those who control an action although not formal parties to it, those whose interests are represented by a party to the action, and possibly coparties to a prior action” may be found to be in privity with a party to a prior action (*Watts v Swiss Bank Corp.*, 27 NY2d 270, 277, 317 NYS2d 315, 320 [1970]).

There is no legal basis for Endo’s argument that the assurance of discontinuance is the equivalent of a stipulation of discontinuance with prejudice. Clearly, the assurance is an enforceable contract between the Attorney General and Endo. By its terms, the Attorney General agreed, without litigation, to resolve the claims that Endo engaged in deceptive consumer practices in violation of General Business Law §§ 349 and 350 in marketing Opana ER in exchange for Endo altering certain business practices. In exercising his authority to enter the assurance, however, the Attorney General retained his right to subsequently commence civil litigation seeking damages, restitution, or injunctive relief against Endo for conduct violating the assurance (*see* Executive Law § 63 [15]), as well as for conduct violating any laws relating to “matters not part of the covered conduct.” It is noted that while evidence of a violation of an assurance is prima facie evidence of a violation of the applicable law in a subsequent civil action or proceeding, it only constitutes such evidence in an action or proceeding brought by the Attorney General (Executive Law § 63 [15]). Moreover, the March 2016 assurance of discontinuance does not immunize Endo from civil actions for subsequent fraudulent activities within New York (*see UBS Sec. LLC v Highland Capital Mgt., L.P.*, 86 AD3d 469, 927 NYS2d 59 [1st Dept 2011]; *Matter of State of New York v Seaport Manor A.C.F.*, 19 AD3d 609, 797 NYS2d 538), or bar the counties from bringing law or equity claims against it for practices within their respective jurisdictions (*see Jane St. Co. v Division of Hous. & Community Renewal*, 165 AD2d 758, 560 NYS2d 193 [1st Dept 1990]). Thus, the doctrine of res judicata does not bar the instant claims against Endo.

Personal Jurisdiction

Actavis contends that the complaint must be dismissed as to Allergan plc because the plaintiffs failed to serve that entity with process; irrespective of such failure, Actavis claims that Allergan plc, which is incorporated in the Republic of Ireland, lacks the necessary contacts with New York so as to permit this court to exercise personal jurisdiction over it. As to the latter point, Actavis alleges that Allergan plc is a holding company that has a headquarters in Dublin, Ireland and an administrative headquarters in Parsippany, New Jersey, that it does not manufacture, market, distribute, or sell any pharmaceutical products, that it is a distinct legal entity that is independent of and operates separately from the entities whose shares it owns, that it does not finance or control the daily affairs of those entities, that it has no corporate records on file in New York, that it has not designated an agent for service of process in New York, that it does not send agents to solicit or conduct business in New York, and that it has no officers or employees in New York.

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The plaintiffs, for their part, acknowledge that Allergan plc was not served with process, but contend that service on Actavis, Inc., as a “mere department” of Allergan plc, was sufficient to support the exercise of jurisdiction over Allergan plc. The plaintiffs also contend that the exercise of personal jurisdiction over Allergan plc is proper because Actavis, Inc. directed its fraudulent marketing activities at New York residents, because Allergan plc is the successor-in-interest to Actavis, Inc. and, therefore, because the jurisdictional contacts of Actavis, Inc. are properly attributable to Allergan plc.

If a defendant challenges the validity of service of a summons and complaint, it is the plaintiff’s burden to prove, by a preponderance of the evidence, that jurisdiction over the defendant was obtained by proper service of process (*Aurora Loan Servs. v Gaines*, 104 AD3d 885, 962 NYS2d 316 [2d Dept 2013]). Likewise, when a motion is made to dismiss an action for lack of personal jurisdiction, it is the plaintiff who bears the ultimate burden of proving a basis for such jurisdiction (*Carrs v Avco Corp.*, 124 AD3d 710, 2 NYS3d 533 [2d Dept 2015]).

Here, the court finds that the plaintiffs failed to meet their burden of establishing that jurisdiction was obtained over Allergan plc by proper service of process. Absent the usual presumption of proper service arising from the process server’s affidavit (*see Wells Fargo Bank, N.A. v Chaplin*, 65 AD3d 588, 884 NYS2d 254 [2d Dept 2009]), it was incumbent on the plaintiffs to produce new evidence to support a finding of jurisdiction. This they failed to do. Although they claim that Actavis, Inc. is a subsidiary “so dominated” by Allergan plc that service on the former was sufficient to base the exercise of jurisdiction over the latter (*see Low v Bayerische Motoren Werke, AG.*, 88 AD2d 504, 449 NYS2d 733 [1st Dept 1982]), they cite as evidence of such domination only that “the headquarters of the two are the same” and that “the corporate officers are the same.” The court finds this evidence insufficient. For effective service of process on a foreign corporation to be accomplished by delivery to a subsidiary, it must appear that the subsidiary is a mere department or arm of its corporate parent, such that the two “are really the same entities in different guises” (*Geffen Motors v Chrysler Corp.*, 54 Misc 2d 403, 404, 283 NYS2d 79, 81 [Sup Ct, Oneida County 1967]).

In order for the subsidiary’s activities to warrant the exercise of jurisdiction over the parent, the parent’s control over the subsidiary’s activities must be so complete that the subsidiary is, in fact, merely a department of the parent. A subsidiary will be considered a mere department only if the foreign parent’s control of the subsidiary is so pervasive that the corporate separation is more formal than real. Generally, there are four factors used in determining whether a subsidiary is a mere department of the foreign parent: (1) common ownership and the presence of an interlocking directorate and executive staff; (2) financial dependency of the subsidiary on the parent; (3) the degree to which the parent interferes in the selection and assignment of the subsidiary’s executive personnel and fails to observe corporate formalities; and (4) the degree of the parent’s control of the subsidiary’s marketing and operational policies.

(*Porter v LSB Indus.*, 192 AD2d 205, 213, 600 NYS2d 867, 872-873 [4th Dept 1993] [internal citations and quotation marks omitted]; *accord Delagi v Volkswagenwerk AG of Wolfsburg, Germany*, 29 NY2d 426, 328 NY2d 653 [1972]). Here, apart from the sharing of corporate headquarters and officers, the

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plaintiffs have not shown, by evidentiary proof, the level of pervasiveness or control necessary to establish prima facie that Actavis, Inc. was a “mere department” of Allergan plc (*cf. Taca Intl. Airlines, S.A. v Rolls-Royce of England*, 15 NY2d 97, 256 NYS2d 129 [1965]). Assuming further, as the plaintiffs theorize alternatively, that Allergan plc is “simply a successor entity to Actavis, Inc.,” it does not appear under New York law that a party’s status as a successor-in-interest to a person properly served will necessarily justify a court’s exercise of personal jurisdiction over that party. Even the federal courts espousing the plaintiffs’ theory recognize that the court obtains jurisdiction only after the plaintiff makes a prima facie showing of successor liability (*e.g. Leon v Shmukler*, 992 F Supp 2d 179 [ED NY 2014]); here the plaintiffs have made no such showing (*see generally Schumacher v Richards Shear Co.*, 59 NY2d 239, 464 NYS2d 437 [1983]). And while a party may withstand a motion to dismiss by demonstrating that essential jurisdictional facts “may exist but cannot then be stated” (CPLR 3211 [d]), here the plaintiffs do not claim that discovery on the issue of personal jurisdiction is necessary (*cf. Goel v Ramachandran*, 111 AD3d 783, 975 NYS2d 428 [2d Dept 2013]).

In light of the foregoing analysis, the court need not determine whether, had service been properly effected, it could exercise general (CPLR 301) or specific (CPLR 302) jurisdiction over Allergan plc.

The court now turns to an examination of the legal sufficiency of the plaintiffs’ causes of action.

First Cause of Action/General Business Law § 349

General Business Law § 349 (a) provides that it is unlawful to perform “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state.” Although the statute’s scope is broad, applying to virtually all types of economic activity (*Karlin v IVF Am., Inc.*, 93 NY2d 282, 290, 690 NYS2d 495, 498 [1999]), its application is strictly limited to deceptive acts or practices leading to consumer transactions in New York (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858 [2002]). Enacted in 1970 to protect New York consumers and to secure “an honest market place where trust prevails between buyer and seller” (*Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 24-25, 623 NYS2d 529, 532 [1995], quoting Mem of Governor Rockefeller, 1970 Legis Ann, at 472), the statute initially was enforceable only by the Attorney General. Subsequently, recognizing that the Attorney General’s resources only allowed for limited enforcement of the consumer protection provisions of General Business Law article 22-A, the Legislature amended the statute to allow private plaintiffs to bring consumer fraud actions (General Business Law § 349 [h]; *Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 205, 785 NYS2d 399, 402 [2004]; *Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 324, 746 NYS2d 858, 863; *Karlin v IVF Am., Inc.*, 93 NY2d 282, 690 NYS2d 495, 499).

To state a cause of action under General Business Law § 349, a plaintiff must allege (1) that the defendant engaged in an act that was directed at consumers, (2) that the act engaged in was materially deceptive or misleading, and (3) that the plaintiff was injured as a result (*Stutman v Chemical Bank*, 95 NY2d 24, 29, 709 NYS2d 892, 895 [2000]; *Oswego Laborers’ Local 214 Pension Fund v Marine*

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Midland Bank, 85 NY2d at 24-25, 623 NYS2d at 532). As to the first element, for pleading purposes, the claim of consumer-oriented conduct must be premised on allegations of facts sufficient to show the challenged acts or practices are “directed at the consuming public” (*Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 343, 704 NYS2d 177, 182 [1999]) or have a broad impact on consumers at large (see *Karlin v IVF Am., Inc.*, 93 NY2d 282, 690 NYS2d 495; *Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 623 NYS2d 529). “Consumer-oriented conduct does not require a repetition or pattern of conduct” (*id.* at 25, 623 NYS2d at 533; see *New York Univ. v Continental Ins. Co.*, 87 NY2d 308, 639 NYS2d 283 [1995]). Sufficient consumer-oriented conduct has been found where a defendant employed “multi-media dissemination of information to the public” (*Karlin v IVF Am., Inc.*, 93 NY2d at 293, 690 NYS2d at 500), or employed an “extensive marketing scheme” that had a broad impact on consumers (*Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d at 344, 704 NYS2d at 182). And though the term “consumers” has been construed to mean those who purchase goods and services for personal, family or household use (see *Benetech, Inc. v Omni Fin. Group, Inc.*, 116 AD3d 1190, 984 NYS2d 186 [3d Dept 2014]), courts have recognized the standing of business entities and business-like entities to sue under General Business Law § 349 for actions and practices which were “directed at or had a broader impact on consumers at large” and caused them harm (see *Accredited Aides Plus, Inc. v Program Risk Mgt., Inc.*, 147 AD3d 122, 46 NYS3d 246 [3d Dept 2017]; *Pesce Bros., Inc. v Cover Me Ins. Agency of NJ, Inc.*, 144 AD3d 1120, 43 NYS3d 85 [2d Dept 2016]; *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96 [2d Dept 2012]; see also *Securitron Magnalock Corp. v Schnabolk*, 65 F3d 256, 265 [2d Cir 1995]). “The critical question [] is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer” (*id.* at 265; see *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96).

As to the second element, a plaintiff must allege the challenged act or practice was “misleading in a material way” (*Stutman v Chemical Bank*, 95 NY2d at 29, 709 NYS2d at 895). “In determining whether a representation or omission is a deceptive act, the test is whether such act is ‘likely to mislead a reasonable consumer acting reasonably under the circumstances’” (*Andre Strishak & Assoc. v Hewlett Packard Co.*, 300 AD2d 608, 609, 752 NYS2d 400, 402 [2d Dept 2002], quoting *Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d at 26, 623 NYS2d at 533; see *Amalfitano v NBTY, Inc.*, 128 AD3d 743, 9 NYS3d 372 [2d Dept 2015]). The statutory phrase “deceptive acts or practices” does not apply to “the mere invention of a scheme or marketing strategy, but [to] the actual misrepresentation or omission to a consumer” (*Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d at 325, 746 NYS2d at 865). Thus, General Business Law § 349 is limited to conduct which undermines a consumer’s ability “to evaluate his or her market options and to make a free and intelligent choice” in the marketplace (*North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d at 13, 953 NYS2d at 102). And while businesses are not required to guarantee that a consumer has all the relevant information specific to its particular situation, an omission-based claim under section 349 is appropriate “where the business alone possesses material information that is relevant to the consumer and fails to provide this information” (*Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d at 26, 623 NYS2d at 533; see *Bildstein v Mastercard Intl., Inc.*, 2005 WL 1324972 [SD NY 2005]). Significantly, while the evidence must show a representation or omission by the offending party likely to mislead a reasonable consumer acting reasonably under the circumstances, the conduct need not

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rise to the level of common-law fraud to be actionable (*Stutman v Chemical Bank*, 95 NY2d at 29, 709 NYS2d at 896; *Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d at 343, 704 NYS2d at 182;), and no proof of intent to defraud by the defendant or justifiable reliance by a consumer is required (see *Koch v Acker, Merrall & Condit Co.*, 18 NY3d 940, 944 NYS2d 422 [2012]; *Small v Lorillard Tobacco Co.*, 94 NY2d 43, 698 NYS2d 615 [1999]; *Oswego Laborers' Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 623 NYS2d 529; *Valentine v Quincy Mut. Fire Ins. Co.*, 123 AD3d 1011, 1 NYS3d 161 [2d Dept 2014]).

As to the third element, a plaintiff is required to allege and prove “actual injury,” though not necessarily pecuniary harm, to such plaintiff as a result of the defendant’s deceptive act or practice (*City of New York v Smokes-Spirits.Com, Inc.*, 12 NY3d 616, 623, 883 NYS2d 772 [2009]; *Stutman v Chemical Bank*, 95 NY2d at 29, 709 NYS2d at 896; *Small v Lorillard Tobacco Co.*, 94 NY2d at 55-56, 698 NYS2d at 620; *Oswego Laborers' Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d at 26, 623 NYS2d at 533; see *Wilner v Allstate Ins. Co.*, 71 AD3d 155, 893 NYS2d 208 [2d Dept 2010]). A plaintiff need not quantify the amount of harm to the public at large or specify consumers who suffered pecuniary loss due to the defendant’s alleged deceptive conduct (see *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96). The courts, however, have rejected efforts to expand the scope of General Business Law § 349 to include recovery for derivative or indirect injuries, finding that a plaintiff asserting such a claim must establish an actual loss or harm that is separate from the deception (see *City of New York v Smokes-Spirits.Com, Inc.*, 12 NY3d 616, 883 NYS2d 772; *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD3d 5, 953 NYS2d 96; *Smith v Chase Manhattan Bank, USA*, 293 AD2d 598, 741 NYS2d 100 [2d Dept 2002]). Stated differently, a plaintiff lacks standing to bring an action under General Business Law § 349 if the claimed loss “arises solely as a result of injuries sustained by another party” (*Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 207, 785 NYS2d 399, 404 [2004]). Thus, an insurer or third-party payor of medical expenditures may not recover derivatively, but must proceed by way of an equitable subrogation action for injuries allegedly suffered by its insured due to a violation of General Business Law § 349 (*id.* at 206, 785 NYS2d at 403).

Initially, contrary to the assertions by the manufacturer defendants, the strict pleading requirements imposed by CPLR 3016 are inapplicable to a cause of action premised on General Business Law § 349 (see *Joannou v Blue Ridge Ins. Co.*, 289 AD2d 531, 735 NYS2d 786 [2d Dept 2001]; *McGill v General Motors Corp.*, 231 AD2d 449, 647 NYS2d 209 [1st Dept 1996]). Moreover, like its sister statute General Business Law § 350, General Business Law § 349 is a remedial statute (*Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d at 207, 785 NYS2d at 403; see *Morelli v Weider Nutrition Group*, 275 AD2d 607, 712 NYS2d 551 [1st Dept 2000]). Thus, it should be “liberally construed to carry out the reforms intended and to promote justice” (McKinney’s Cons Laws of NY, Book 1, Statutes § 321).

The court finds the allegations in the complaint are legally sufficient to state a cause of action under General Business Law § 349 as against each of the manufacturer defendants. The plaintiffs allege the manufacturer defendants employed assiduously crafted, multi-pronged marketing strategies that targeted the general public through websites, print advertisements, and educational materials and

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publications as part of their respective campaigns to change the perception of the risks associated with prescription opioids and to de-stigmatize and normalize the long-term use of opioids for chronic nonmalignant pain. According to the complaint, to perpetuate an increase in the amount and dosage of opioid prescriptions written for patients, and to optimize the market share for their respective products, the manufacturer defendants also aggressively targeted physicians and other prescribers, essential conduits in the sale of prescription opioids to the public, by having their sales representatives “detail” prescribers in face-to-face meetings, by inviting prescribers to attend informational programs, by hiring “product loyalists” to serve as paid speakers for such programs, and by using data mining to track opioid prescriptions and reward prolific prescribers of their products. Other alleged marketing strategies designed to affect physicians’ prescribing practices included advertising in print journals and online, sponsoring continuing medical education courses, and hiring so-called “key opinion leaders” (KOLs) to act as consultants and serve as lecturers.

The plaintiffs further allege that the manufacturer defendants’ marketing campaigns included funding so-called “front groups,” such as the American Pain Foundation and the American Academy of Pain Medicine, which wrote and disseminated favorable educational materials, published “scientific literature” without scientific bases, and created opioid treatment guidelines supporting opioid therapy for chronic pain. According to the complaint, in addition to providing those groups with substantial funding, the manufacturer defendants exercised significant influence over the educational programs and written materials, such as journal articles and treatment guidelines, regarding opioids presented by front groups and KOLs. Moreover, the plaintiffs allege that the manufacturer defendants sponsored websites created by front groups and accessible by the public that promoted prescription opioids as a means for improving patients’ normal daily functions and quality of life. Such allegations are sufficient to plead consumer-oriented conduct within the scope of General Business Law § 349 (see *Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 704 NYS2d 177; *Karlin v IVF Am., Inc.*, 93 NY2d 282, 690 NYS2d 495; *Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d 20, 623 NYS2d 529; *Accredited Aides Plus, Inc. v Program Risk Mgt., Inc.*, 147 AD3d 122, 46 NYS3d 246 [3d Dept 2017]). The court rejects the manufacturer defendants’ argument that, as only physicians and other medical providers can prescribe prescription drugs, misrepresentations concerning the risks and benefits of opioids made in connection with their marketing campaigns cannot constitute “consumer-oriented” conduct under the informed or knowledgeable intermediary doctrine, a defense against a failure to warn claim (see *Martin v Hacker*, 83 NY2d 1, 607 NYS2d 598 [1993]; cf. *Amos v Biogen Idec Inc.*, 28 F Supp 3d 164 [WD NY 2014]).

The plaintiffs also sufficiently allege materially deceptive acts and practices by the manufacturer defendants that undermined consumers’ ability to assess the benefits and dangers of prescription opioids and to make informed decisions as to the efficacy and safety of opioid therapy for chronic pain (see *Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *Gaidon v Guardian Life Ins. Co. of Am.*, 94 NY2d 330, 704 NYS2d 177; *Goldman v Simon Prop. Group, Inc.*, 58 AD3d 208, 869 NYS2d 125 [2d Dept 2008]). Among the numerous allegations of materially deceptive practices set forth in the complaint are claims that the manufacturer defendants made and disseminated statements online, in personal presentations, in advertisements, in publications, and in educational materials that misrepresented the risks of opioid addiction and falsely portrayed prescription opioids as a preferred

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treatment option for chronic pain, in particular by depicting such drugs as appropriate for long-term use and effective in improving patients' quality of life and ability to function on a day-to-day basis. The plaintiffs allege the manufacturer defendants fallaciously promoted the concept of pseudoaddiction to allay physicians' and patients' concerns about the addictiveness of prescription opioids and to destigmatize their use, and deliberately omitted information regarding potential adverse effects, including abuse and addiction, from promotional publications and presentations. They also allege that the manufacturer defendants employed front groups and KOLs to disseminate misleading information through educational forums, publications and websites that reinforced their marketing messages, and to deceive the medical community and the public about the effectiveness of opioids in treating chronic pain, the proper dosing and titration of opioids, and the danger of addiction. In addition, the plaintiffs allege that the misleading communications by the manufacturer defendants, the front groups, and the KOLs were made or disseminated within the plaintiff counties or were posted on public websites. The manufacturer defendants' argument that the plaintiffs must allege and prove a particular misstatement led a specific physician to write a particular opioid prescription for a patient is rejected (*see generally North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD2d 5, 953 NYS2d 96).

Moreover, the plaintiffs adequately allege that the plaintiffs suffered direct injuries as a result of the manufacturer defendants' alleged materially deceptive acts or practices (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *North State Autobahn, Inc. v Progressive Ins. Group Co.*, 102 AD2d 5, 953 NYS2d 96; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1051642 [D Mass 2007]). Contrary to the assertions by the manufacturer defendants, it is sufficiently alleged that the plaintiffs, as a result of the manufacturer defendants' deceptive marketing campaigns regarding opioid effectiveness, misuse and addiction, paid for medications that were not medically necessary and that would not have been approved for the treatment of chronic, non-cancer pain if all the relevant facts about such medications had been known by them. The plaintiffs allege, for example, that they paid for brand-name opioid prescriptions, such as OxyContin, Opana, Nucynta, and Kadian, for employees covered by county-funded health insurance plans and for residents receiving Medicaid benefits based on material misrepresentations disseminated by the manufacturer defendants to the public and the health care community that such products had lower potential for abuse and addiction based on their supposed "long-acting" or "steady-state" properties, and that they paid for brand-name prescriptions of "rapid-onset" or short-acting opioids, such as Actiq, Fentora, and Duragesic, based on material misrepresentations that such medications are safe for treating non-cancer, chronic-pain patients complaining of "breakthrough" pain episodes (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *cf. Baron v Pfizer, Inc.*, 42 AD3d 627, 840 NYS2d 445 [3d Dept 2007]). Similarly, the plaintiffs allege that they paid for prescriptions of OxyContin and Opana based on Purdue's and Endo's misrepresentations that such medications were tamper-resistant or crush-proof and, therefore, less likely to be abused (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *cf. Baron v Pfizer, Inc.*, 42 AD3d 627, 840 NYS2d 445). It further can be inferred from the complaint that the plaintiffs, having been deceived by the defendant manufacturers about the risks associated with long-term prescription opioid use, were injured by having to pay for more prescriptions than would have otherwise been necessary as patients, particularly county employees and Medicaid beneficiaries, became addicted to such painkillers (*see Wilner v Allstate Ins. Co.*, 71 AD3d 155, 893 NYS2d 208 [2d Dept 2010]). In addition, it is alleged that the manufacturer defendants' deceptive

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marketing campaigns created a public health crisis within the plaintiff counties, leading to substantial increases in opioid addiction, abuse, overdose and death among residents, and that such crisis has forced the plaintiffs to allocate substantial resources to implement measures to reduce opioid abuse and opioid-related crimes, and to combat opioid addiction and overdoses with medications, such as naltrexone, naloxone, and buprenorphine, and with treatment programs. Thus, the plaintiffs here are not simply seeking to recoup medical and drug costs incurred by their employees and Medicaid beneficiaries (*cf. Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 785 NYS2d 399).

Second Cause of Action/General Business Law § 350

Having a scope as broad as that of General Business Law § 349 (*Karlin v IVF Am., Inc.*, 93 NY2d at 290, 690 NYS2d at 498), the statute defines false advertising as “advertising, including labeling, of a commodity” which is “misleading in a material respect.” As with a General Business Law § 349 claim, a plaintiff asserting a claim under this statute must establish that the alleged false advertisement had an impact on consumers at large, was deceptive or misleading in a material way, and caused injury (*Andre Strishak & Assoc. v Hewlett Packard Co.*, 300 AD2d at 609, 752 NYS2d at 402; *Scott v Bell Atl. Corp.*, 282 AD2d 180, 183-184, 726 NYS2d 60, 63 [1st Dept 2001], *lv granted in part, dismissed in part* 97 NY2d 698, 739 NYS2d 95, *mod* 98 NY2d 314, 747 NYS2d 858 [2002]). General Business Law § 350-a (1) provides that, in determining whether advertising is misleading, “there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal [material facts] in the light of such representations with respect to the commodity . . . to which the advertising relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.” The defendant’s conduct need not rise to the level of a fraud to be actionable (*Matter of People v Applied Card Sys., Inc.*, 27 AD3d 104, 107, 805 NYS2d 175, 178 [3d Dept 2005]). Further, a claim of false advertising must be premised on an advertisement published within the state that “is likely to mislead a reasonable consumer acting reasonably under the circumstances” (*Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank*, 85 NY2d at 26, 623 NYS2d at 533). Reliance by the plaintiff on an advertisement is not a required element of a General Business Law § 350 claim (*Koch v Acker, Merrall & Condit Co.*, 18 NY3d 940, 941, 944 NYS2d 452, 453 [2012]; *Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d at 324 n. 1, 746 NYS2d 858, 865; *but see Pesce Bros., Inc. v Cover Me Ins. Agency of NJ, Inc.*, 144 AD3d 1120, 43 NYS3d 85); rather, the plaintiff must show the false advertisement caused it to suffer injury or loss (*cf. Stutman v Chemical Bank*, 95 NY2d 24, 709 NYS2d 892).

Here, the plaintiffs sufficiently allege that the manufacturer defendants, through branded and unbranded print advertisements, public websites, and patient education materials, as well as through one-on-one contacts between sales representatives and physicians, made materially misleading statements regarding the benefits of prescription opioid therapy for chronic pain and the risks associated with opioid use, particularly the potential for abuse (*see Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 746 NYS2d 858; *Karlin v IVF Am., Inc.*, 93 NY2d 282, 290, 690 NYS2d 495). It is alleged, among other things, that, as marketing research showed physicians are more likely to prescribe a drug if specifically requested by a patient, the manufacturer defendants published misleading advertisements for both the

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general consuming public and prescribers. According to the complaint, false advertising was conducted by the manufacturer defendants directly, through branded print and online advertisements and through detailing, and indirectly, through unbranded advertisements, public websites, and various publications issued by front groups funded and controlled by such defendants. The plaintiffs allege, for example, that Purdue and Endo falsely advertised OxyContin and Opana as tamper-resistant and less prone to abuse; that Purdue, Endo, Janssen, and Actavis falsely advertised their respective brand drugs, namely OxyContin, MS Contin, Nucynta ER, Duragesic, Opana ER, and Kadian, as providing up to 12 hours of pain relief; and that Cephalon falsely advertised Actiq and Fentora as appropriate treatment for all cancer patients suffering from breakthrough pain, not only those who were opioid tolerant; and all defendants failed to reveal the substantial dangers associated with long-term use of such potent drugs. It is alleged the manufacturer defendants falsely represented on public websites aimed at patients and prescribers that warnings about the risks of opioid addiction were “overstated,” and promoted the concept of pseudoaddiction, for which there is no scientific basis. Further, the plaintiffs allege that the false advertisements materially misled consumers and prescribers about the benefits and risks of prescription opioid therapy for chronic pain, including by failing to reveal that opioids pose a higher risk of abuse and addiction than other analgesics and that there was no scientific basis for many of the claims contained therein.

As to the “impact on consumers” element of General Business Law § 350, the allegations in the complaint are sufficient to infer that false advertising by the manufacturer defendants dramatically increased consumer demand for and consumption of prescription opioids, and that it created public misperception about the safety and efficacy of such prescription drugs. As to the causation element, the allegations in the complaint are sufficient to infer that the opioid epidemic allegedly spawned in part by the manufacturer defendants’ false advertising caused the plaintiffs to suffer extraordinary losses, including the costs related to the care and treatment of residents suffering from prescription opioid addiction, and the costs of opioid prescriptions for employees receiving county-funded health insurance benefits and residents receiving Medicaid benefits that would not have been approved had the risks associated with long-term opioid therapy for chronic, non-cancer related pain been known (*see Karlin v IVF Am., Inc.*, 93 NY2d 282, 690 NYS2d 495; *cf. Stutman v Chemical Bank*, 95 NY2d 24, 709 NYS2d 892).

Third Cause of Action/Public Nuisance

The manufacturer defendants jointly contend that the plaintiffs’ third cause of action, alleging public nuisance, is deficient as a matter of law for failure to plead either proximate causation or substantial interference with a public right. As to proximate causation, they contend that the alleged causal link between their conduct and the plaintiffs’ injury is too attenuated to state a valid claim. As to substantial interference with a public right, they contend that their production, promotion, and marketing of lawful, FDA-approved medications is not “interference,” and that the concept of “public right” is not so broad as to include a right to be free of the threat that some individuals might use the product in a way that might create a risk of harm.

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A public or “common” nuisance is an offense against the State and is subject to abatement or prosecution on application of the proper governmental agency (*Copart Indus. v Consolidated Edison Co. of N.Y.*, 41 NY2d 564, 394 NYS2d 169 [1977]). It consists of conduct or omissions which offend, interfere with, or cause damage to the public in the exercise of rights common to all, in a manner such as to offend public morals, interfere with use by the public of a public place, or endanger or injure the property, health, safety or comfort of a considerable number of persons (*id.*).

Section 821B of Restatement (Second) of Torts provides:

(1) A public nuisance is an unreasonable interference with a right common to the general public.

(2) Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:

(a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or

(b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or

(c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.

The manufacturer defendants’ arguments are insufficient to warrant dismissal. Addressing first the claimed lack of proximate causation, the defendants rely heavily on *People v Sturm, Ruger & Co.* (309 AD2d 91, 761 NYS2d 192, *lv denied* 100 NY2d 514, 769 NYS2d 200 [2003]), a case involving public nuisance claims against handgun manufacturers, wholesalers, and retailers. There, the plaintiff alleged, in part, that despite the defendants having been placed on notice that the guns sold, distributed, and marketed by them were being used in crimes, they were deliberately designing and marketing their product in a way that placed a disproportionate number of guns in the possession of people who use them unlawfully. In dismissing the public nuisance claims, the court, based on its reading of *Hamilton v Beretta U.S.A. Corp.* (96 NY2d 222, 727 NYS2d 7 [2002] [involving a negligent marketing claim against handgun makers]), relied primarily on a proximate cause analysis, noting that the harms alleged were too indirect and remote from the defendants’ conduct and expressing a general reluctance to “open the courthouse doors to a flood of limitless, similar theories of public nuisance” in matters involving commercial activity (*People v Sturm, Ruger & Co.*, 309 AD2d at 96, 761 NYS2d at 196). The court did, however, recognize that public nuisance might be an appropriate tool, in other contexts, to address consequential harm from commercial activity. And the court also noted, as in *Hamilton*, a break in the causative chain by the criminal activity of intervening third parties, i.e., that the parties most directly responsible for the unlawful use of handguns were the individuals unlawfully using them.

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Here, by contrast, it is alleged that the plaintiffs have been damaged not only by the illegal use of opioids but also by their legal use, consistent with the manufacturer defendants' marketing and promoting. As to such legal use, it is at least arguable that the manufacturer defendants were in a position to anticipate or prevent the claimed injuries; it does not seem unfair, therefore, to hold them potentially accountable. The court is doubtful, in any event, whether a discussion of proximate cause in a case based on negligence should even apply in a case based on public nuisance. "[W]here the welfare and safety of an entire community is at stake, the cause need not be so proximate as in individual negligence cases" (*City of New York v A-1 Jewelry & Pawn*, 247 FRD 296, 347-348 [ED NY 2007]). As for the manufacturer defendants' claim that the plaintiffs have failed to plead substantial interference with a public right, it suffices to note the defendants' failure to establish why public health is not a right common to the general public, nor why such continuing, deceptive conduct as alleged would not amount to interference; it can scarcely be disputed, moreover, that the conduct at the heart of this litigation, alleged to have created or contributed to a crisis of epidemic proportions, has affected "a considerable number of persons" (*Copart Indus. v Consolidated Edison Co. of N.Y.*, 41 NY2d at 568, 394 NYS2d at 172).

Fourth Cause of Action/Social Services Law § 145-b

The manufacturer defendants jointly contend that the plaintiffs' fourth cause of action, alleging violation of Social Services Law § 145-b, must be dismissed for failure to state a cause of action. The manufacturer defendants claim that the plaintiffs failed to plead facts showing that any defendant "attempt[ed] to obtain" or "obtain[ed] payment from public funds," or that they made any "false statement or representation." As to the pleading requirement with respect to false statements or representations, the manufacturer defendants note the plaintiffs' failure to identify any "claim for payment" made to the plaintiffs by any defendant or any specific "acknowledgment, certification, claim, ratification or report of data which serve[d] as the basis for a claim," or to allege that any such statement or representation was materially or knowingly false. Although the plaintiffs duly recite the elements of the cause of action in their complaint, the manufacturer defendants claim that such formulaic recitation is insufficient to withstand dismissal. The manufacturer defendants further claim that Social Services Law § 145-b applies only to providers and not to parties who, like the defendants, do not directly receive public funds.

The plaintiffs counter that their complaint does, in fact, plead each of the required elements, and that a cause of action alleging a violation of Social Services Law § 145-b need not be pleaded with the same degree of detail as a cause of action in fraud. The plaintiffs also contend that the statute is not limited in its application to Medicaid providers who receive direct payments of public funds but applies to any person who makes fraudulent statements to obtain such funds, whether directly or indirectly.

Social Services Law § 145-b states that "[i]t shall be unlawful for any person, firm or corporation knowingly by means of false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished" under the Social Services Law. A "statement or representation" includes, but is not limited to

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a claim for payment submitted to the State, a political subdivision of the state, or an entity performing services under contract to the state or a political subdivision of the state; an acknowledgment, certification, claim, ratification or report of data which serves as the basis for a claim or a rate of payment[;] financial information whether in a cost report or otherwise[;] health care services available or rendered[;] and the qualifications of a person that is or has rendered health care services.

(Social Services Law § 145-b [1] [b]; *see generally State of New York v Lutheran Ctr. for the Aging*, 957 F Supp 393 [ED NY 1997]). A person, firm or corporation “has attempted to obtain or has obtained” payment from public funds “when any portion of the funds from which payment was attempted or obtained are public funds, or any public funds are used to reimburse or make prospective payment to an entity from which payment was attempted or obtained” (Social Services Law § 145-b [1] [c]). The statute vests the local social services district or the State the right to recover civil damages for Medicaid and Medicare fraud equal to “three times the amount by which any figure is falsely overstated or in the case of non-monetary false statements or representations, three times the amount of damages which the state, political subdivision of the state, or entity performing services under contract to the state or political subdivision of the state sustain as a result of the violation or five thousand dollars, whichever is greater” (Social Services Law § 145-b [2]).

The manufacturer defendants’ claims are rejected. To the extent they contend that this cause of action is deficient due to lack of factual specificity, the court is constrained to disagree. Even assuming the applicability of CPLR 3016 (b), which requires that causes of action based in fraud be pleaded with particularity, the pleading is sufficient. As discussed elsewhere in this order, the complaint adequately alleges the fraudulent and deceptive practices underlying the causes of action alleging violations of General Business Law §§ 349 and 350, as well as the cause of action for fraud; it is enough, therefore, for purposes of CPLR 3016 (b), to allege, as the plaintiffs have done, that the manufacturer defendants employed those practices to obtain or attempt to obtain public funds for themselves or others. “[T]he purpose underlying [CPLR 3016 (b)] is to inform a defendant of the complained-of incidents . . . CPLR 3016 (b) is satisfied when the facts suffice to permit a reasonable inference of the alleged misconduct” (*Eurycleia Partners v Seward & Kissel*, 12 NY3d 553, 559, 883 NYS2d 147, 150 [2009] [internal quotation marks omitted]). Nor, contrary to the manufacturer defendants’ argument, is there any pleading requirement that the plaintiffs allege facts showing that the defendants obtained or attempted to obtain public funds directly from the plaintiffs. Under subdivision (1) (a), it is unlawful for a person to fraudulently obtain or attempt to obtain public funds, whether “on behalf of himself or others”; under subdivision (1) ©, a person has obtained or attempted to obtain public funds when such funds “are used to reimburse or make prospective payment to an entity from which payment was obtained or attempted.” If, then, a defendant indirectly receives public funds by making a fraudulent statement to assist a Medicaid provider in procuring such funds, such conduct would seem to fall within the ambit of the statute (*cf. In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F Supp 2d 165 [D Mass 2004]). Even if *People v Pharmacia Corp.* (2004 WL 5841904 [Sup Ct, Albany County 2004]), cited by the manufacturer defendants, may be to the contrary—and this court is not persuaded that it is—it suffices to

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note at this juncture that a decision of a court of equal jurisdiction, though entitled to respectful consideration, is not controlling (McKinney's Cons Laws of NY, Book 1, Statutes § 72 [b]). Likewise, it cannot be said that the plaintiffs failed to plead a "false statement or representation." While the manufacturer defendants correctly note that a "statement or representation" within the definition of the statute may include a "claim for payment" or an "acknowledgment, certification, claim, ratification or report of data" which serves as the basis for such a claim, the statute does not exclude, by its terms, statements and representations which are just that—statements and representations—and the defendants do not explain why the allegedly false statements and representations underlying the plaintiffs' other causes of action based in fraud and deceit would not serve to support this cause of action as well. Whether, then, the plaintiffs may have failed to identify specifically any "claim for payment" made to a county or any "acknowledgment, certification, claim, ratification or report of data" serving as the basis for such a claim is immaterial for purposes of this determination.

Fifth Cause of Action/Fraud

The manufacturer defendants move to dismiss the plaintiffs' fifth cause of action for fraud on the grounds, among other things, that the complaint does not conform to the pleading requirements of CPLR 3013 and CPLR 3016 (b). CPLR 3013 provides that the "[s]tatements in a pleading shall be sufficiently particular to give the court and the parties notice of the transactions, occurrences, or series of transactions or occurrences, intended to be proved and the material elements of each cause of action or defense." Here, the manufacturer defendants have not indicated that the complaint fails to give them adequate notice of the transactions, occurrences, or series of transactions or occurrences which the plaintiffs intend to prove regarding their fifth cause of action, or that they are unable to frame an answer to the allegations in the complaint.

CPLR 3016 (b) requires that in an action based upon fraud, "the circumstances constituting the wrong shall be stated in detail" in the pleading. Bare allegations of fraud without any allegation of the details constituting the wrong are not sufficient to sustain such a cause of action (CPLR 3016 [b]; *see Kline v Taukpoint Realty Corp.*, 302 AD2d 433, 754 NYS2d 899 [2d Dept 2003]; *Gill v Caribbean Home Remodeling*, 73 AD2d 609, 422 NYS2d 448 [2d Dept 1979]; *Biggar v Buteau*, 51 AD2d 601, 377 NYS2d 788 [3d Dept 1976]). However, the statute "requires only that the misconduct complained of be set forth in sufficient detail to clearly inform a defendant with respect to the incidents complained of" (*Lanzi v Brooks*, 43 NY2d 778, 780, 402 NYS2d 384, 385 [1978]; *see also Mandarin Trading Ltd. v Wildenstein*, 16 NY3d 173, 919 NYS2d 465 [2011]; *Mikulski v Battaglia*, 112 AD3d 1355, 977 NYS2d 839 [4th Dept 2013]). In addition, when the operative facts are "peculiarly within the knowledge of the party" alleged to have committed the fraud, it may not be possible at the pleading stage of the proceeding for the plaintiff to detail all the circumstances constituting the fraud (*Jered Contr. Corp. v New York City Tr. Auth.*, 22 NY2d 187, 194, 292 NYS2d 98, 104 [1968]; *see also Pludeman v Northern Leasing Sys., Inc.*, 10 NY3d 486, 860 NYS2d 422 [2008]). It has been held that CPLR 3016 (b) is satisfied when the facts suffice to permit a "reasonable inference" of the alleged misconduct (*Eurycleia Partners, LP v Seward & Kissel, LLP*, 12 NY3d 553, 883 NYS2d 147 [2009], citing *Pludeman v Northern Leasing Sys., Inc.*, 10 NY3d 486, 860 NYS2d 422).

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The elements of a cause of action for fraud are (1) a misrepresentation of fact, (2) which was false and known to be false by the defendant, (3) made for the purpose of deceiving the plaintiff, (4) upon which the plaintiff justifiably relied, (5) causing injury (*e.g. Clearview Concrete Prods. Corp. v S. Charles Gherardi, Inc.*, 88 AD2d 461, 453 NYS2d 750 [2d Dept 1982]; *see also Ozelkan v Tyree Bros. Envtl. Servs.*, 29 AD3d 877, 815 NYS2d 265 [2d Dept 2006]). Thus, a plaintiff seeking to recover for fraud must establish that the defendant knowingly made a false representation (*see e.g. Wilson v Neighborhood Restore Hous.*, 129 AD3d 948, 12 NYS3d 166 [2d Dept 2015]; *Miller v Livingstone*, 25 AD2d 106, 267 NYS2d 249 [1st Dept], *affd* 18 NY2d 967, 278 NYS2d 206 [1966]), that the defendant made such misrepresentation with an intent to defraud (*Marine Midland Bank v Russo Produce Co., Inc.*, 50 NY2d 31, 427 NYS2d 961 [1980]), and that the misrepresentation was false in a material and substantial respect (*see Ozelkan v Tyree Bros. Envtl. Servs., Inc.*, 29 AD3d 877, 815 NYS2d 265). A plaintiff alleging fraud also must prove that it relied on the alleged misrepresentation and that such misrepresentation was a substantial factor in inducing it to act (*see Ginsburg Dev. Cos., LLC v Carbone*, 134 AD3d 890, 22 NYS3d 485 [2d Dept 2015]). Significantly, the plaintiff's reliance on the misrepresentation must have been reasonable or justified under the circumstances (*see McDonald v McBain*, 99 AD3d 436, 952 NYS2d 486 [1st Dept 2012]; *East End Cement & Stone, Inc. v Carnevale*, 73 AD3d 974, 903 NYS2d 420 [2d Dept 2010]). Reliance will not be justified if the plaintiff could have discovered the truth through due diligence (*see Wildenstein v 5H&Co., Inc.*, 97 AD3d 488, 950 NYS2d 3 [1st Dept 2012]).

The plaintiffs have pled a cognizable cause of action for fraud. The plaintiffs allege that the manufacturer defendants purposefully misrepresented that opioids improve function and quality of life, that addiction risks can be managed, that withdrawal is easily managed, that higher doses of opioids pose no greater risks to patients, and that they deceptively minimized the adverse effects of opioids while overstating the risks of NSAIDs (nonsteroidal anti-inflammatory drugs). The plaintiffs further allege that the manufacturer defendants created a body of false, misleading, and unsupported medical and popular literature about opioids, that they disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations, and that they spent “hundreds of millions of dollars” in this false and misleading marketing campaign to improperly influence individual prescribers. The plaintiffs allege that the strategies employed by the manufacturer defendants “were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns.”

The plaintiffs also allege that the manufacturer defendants’ “misrepresentations were material to, and influenced, the plaintiffs’ decisions to pay claims for opioids for chronic pain (and, therefore, to bear its consequential costs in treating overdose, addiction, and other side effects of opioid use),” and that the plaintiffs have taken “steps to ensure that the opioids are only prescribed and covered when medically necessary or reasonably required.” Thus, the plaintiffs allege that the manufacturer defendants intended that the plaintiffs, physicians, patients, and others would rely on their misrepresentations and omissions, and that the plaintiffs reasonably relied upon said misrepresentations and omissions.

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Finally, the plaintiffs allege that the manufacturer defendants' misrepresentations caused them direct injury as they have incurred costs related to opioid addiction and abuse, including health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. As discussed above, to the extent the manufacturer defendants urge the application of the rule barring recovery of indirect or derivative injuries sustained by others, the court notes that the plaintiffs are not simply seeking to recoup medical and drug costs incurred by their employees and Medicaid beneficiaries (*cf. Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 205, 785 NYS2d 399 [2004]).

Sixth Cause of Action/Unjust Enrichment

The manufacturer defendants contend that the plaintiffs' sixth cause of action, sounding in unjust enrichment, must be dismissed because it is derivative and duplicative of their other claims, and because the plaintiffs have failed to allege facts showing that the defendants were enriched, that such enrichment was unjust and at the plaintiffs' expense, that the plaintiffs suffered any cognizable loss, or that it would be against equity or good conscience to permit the manufacturer defendants to retain what it sought to be recovered. The manufacturer defendants also contend that the parties lack a sufficiently close relationship to support a cause of action for unjust enrichment.

In order to adequately plead a cause of action for unjust enrichment, it must be alleged that the defendant was enriched, at the plaintiff's expense, and that it is against equity and good conscience to permit the defendant to retain what is sought to be recovered (*Mandarin Trading v Wildenstein*, 16 NY3d 173, 919 NYS2d 465 [2011]). The theory of unjust enrichment "lies as a quasi-contract claim" and contemplates "an obligation imposed by equity to prevent injustice, in the absence of an actual agreement between the parties" (*Georgia Malone & Co. v Rieder*, 19 NY3d 511, 516, 950 NYS2d 333, 336 [2012] [internal quotation marks omitted]). "Although privity is not required for an unjust enrichment claim, a claim will not be supported if the connection between the parties is too attenuated" (*Mandarin Trading v Wildenstein*, 16 NY3d at 182, 919 NYS2d at 472; *accord Sperry v Crompton Corp.*, 8 NY3d 204, 831 NYS2d 760 [2007]).

Here, the plaintiffs plead that the manufacturer defendants, as an expected and intended result of their conscious wrongdoing alleged elsewhere in the complaint, were enriched from opioid purchases made by the plaintiffs and that it would be unjust and inequitable to permit them to enrich themselves at the plaintiffs' expense.

The court finds the pleading sufficient to withstand the manufacturer defendants' claims. It does not appear, for purposes of this determination, that this cause of action is either derivative or duplicative of any other cause of action. As pleaded, it is the only cause of action by which the plaintiff seek disgorgement of profits and other monetary benefits resulting from the manufacturer defendants' alleged misconduct; moreover, as New York law specifically allows for the pleading of alternative causes of action and alternative forms of relief (CPLR 3014, 3017), the plaintiffs need not elect any theory over another at this preliminary stage. To the extent the manufacturer defendants urge the application of the rule barring recovery of indirect or derivative injuries sustained by others, the court notes, as before, that

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the plaintiffs here are not simply seeking to recoup medical and drug costs incurred by their employees and Medicaid beneficiaries (*cf. Blue Cross & Blue Shield of N.J., Inc. v Philip Morris USA Inc.*, 3 NY3d 200, 785 NYS2d 399 [2004]). The manufacturer defendants have also failed to explain why, as a pleading matter, the retention of profits wrongfully obtained would not be unjust. As for the relationship between and among the parties, the plaintiffs allege, in relevant part, that the manufacturer defendants created a body of false and misleading literature intended to shape the perceptions of third-party payors such as the plaintiffs, encouraging them to pay for long-term opioid prescriptions and effectively depriving them of the chance to exercise informed judgment; implicit in those allegations is that the manufacturer defendants knew the plaintiffs were to be the source of a significant portion of their profits. Accepting those facts as true and according the plaintiffs the benefit of every favorable inference (*Leon v Martinez*, 84 NY2d 83, 614 NYS2d 972 [1994]), it is evident that the plaintiffs have pleaded a relationship—or “at least an awareness” by the manufacturer defendants of the plaintiffs’ existence (*Mandarin Trading v Wildenstein*, 16 NY3d at 182, 919 NYS2d at 472)—sufficient to maintain their cause of action.

Seventh Cause of Action/Negligence

To prove a prima facie case of negligence, a plaintiff must demonstrate the existence of a duty, a breach of that duty, and that the breach of such duty was a proximate cause of his or her injuries (*see Pulka v Edelman*, 40 NY2d 781, 390 NYS2d 393 [1976]; *see also Pasquaretto v Long Is. Univ.*, 106 AD3d 794, 964 NYS2d 599 [2d Dept 2013]; *Schindler v Ahearn*, 69 AD3d 837, 894 NYS2d 462 [2d Dept 2010]). A duty of reasonable care owed by the alleged tortfeasor to the plaintiff is essential to any recovery in negligence (*Eiseman v State of New York*, 70 NY2d 175, 187, 518 NYS2d 608 [1987]; *see Espinal v Melville Snow Contrs.*, 98 NY2d 136, 746 NYS2d 120 [2002]). Although juries determine whether and to what extent a particular duty was breached, it is for the courts to decide in the first instance whether any duty exists and, if so, the scope of such duty (*Church v Callanan Indus.*, 99 NY2d 104, 752 NYS2d 254 [2002]; *Darby v Compagnie Natl. Air France*, 96 NY2d 343, 728 NYS2d 731 [2001]; *Waters v New York City Hous. Auth.*, 69 NY2d 225, 513 NYS2d 356 [1987]).

The manufacturer defendants contend that the plaintiffs’ cause of action for negligence must be dismissed because New York does not impose a duty upon manufacturers to refrain from the lawful distribution of a non-defective product. Citing *Hamilton v Beretta U.S.A. Corp.*, 96 NY2d 222, 727 NYS2d 7 (2001), they also argue that they do not owe the plaintiffs a duty to protect against the misconduct of third parties, that New York does not impose a legal duty on manufacturers to control the distribution of potentially dangerous products, and that “the alleged foreseeability of injuries is not a reason to find that a duty exists” herein. They further contend that the plaintiffs must allege a “specific duty” is owed to them, and that they may not rely upon a “general duty to society” to support their cause of action for negligence.

“A critical consideration in determining whether a duty exists is whether ‘the defendant’s relationship with either the tortfeasor or the plaintiff places the defendant in the best position to protect against the risk of harm’” (*Davis v South Nassau Communities Hosp.*, 26 NY3d 563, 572, 26 NYS2d 231 [2015], quoting *Hamilton v Beretta U.S.A. Corp.*, 96 NY2d 222, 233, 727 NYS2d 7 [2001]).

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Unlike *Hamilton*, where the Court of Appeals found that gun manufacturers were not in the best position to protect against the risk of harm from the misuse of its product by third parties, here the plaintiffs allege facts sufficient to support the existence of a duty of care. Specifically, the plaintiffs allege that because the manufacturer defendants had knowledge of the actual risks and benefits of their products, including their addictive nature, which they did not disclose, they were in the best position to protect the plaintiffs against the expenses incurred for opioids prescribed for their employees and for Medicaid beneficiaries that would not have been approved for payment, and against the extraordinary amounts expended to combat the opioid crisis allegedly caused by the deceptive marketing campaigns.

Courts traditionally “fix the duty point by balancing factors, including the reasonable expectations of parties and society generally, the proliferation of claims, the likelihood of unlimited or insurer-like liability, disproportionate risk and reparation allocation, and public policies affecting the expansion or limitation of new channels of liability” (*Palka v Servicemaster Mgt. Servs. Corp.*, 83 NY2d 579, 586, 611 NYS2d 817, 821 [1994]; see *Tagle v Jakob*, 97 NY2d 165, 737 NYS2d 331 [2001]). In balancing these factors, the plaintiffs have adequately pled that their expectations and those of society would require different behaviors on the part of the manufacturer defendants, that there is a finite number of counties in the State of New York with potential claims against said defendants, that the allegedly negligent acts and omissions of said defendants do not create unlimited liability, that the risks allegedly created by said defendants do not disproportionately outweigh the possible reparations to be awarded herein, and that public policy must address the issues raised in the complaint. It is noted that New York courts have recognized a cause of action for negligent marketing of prescription drugs (see *Bikowicz v Sterling Drug, Inc.*, 161 AD2d 982, 557 NYS2d 551 [3d Dept 1990]).

The plaintiffs also allege sufficient facts to support a separate duty not to deceive (see e.g. *Cipollone v Liggett Group, Inc.*, 505 US 504, 112 S Ct 2608 [1992]; *In re Ford Fusion & C-Max Fuel Econ. Litig.*, 2015 WL 7018369 [SD NY 2015]; see also *Tomasino v American Tobacco Co.*, 23 AD3d 546, 807 NYS2d 603 [2d Dept 2005]). The plaintiffs allege that the manufacturer defendants failed to comply with 10 NYCRR 80.22, which requires manufacturers of controlled substances to “establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” It is well settled that a violation of a regulation or ordinance constitutes some evidence of negligence (see *Bauer v Female Academy of Sacred Heart*, 97 NY2d 445, 741 NYS2d 491 [2002]; *March Assoc. Constr., Inc. v CMC Masonry Constr.*, 151 AD3d 1050, 58 NYS3d 423 [2d Dept 2017]). A “violation of the statute’s implementing rules and regulations . . . constitutes some evidence of negligence” (*Watral & Sons, Inc. v OC Riverhead 58, LLC*, 34 AD3d 560, 567, 824 NYS2d 392, 398 [2d Dept 2006], *revd on other grounds* 10 NY3d 180, 855 NYS2d 49 [2008]).

Moreover, the manufacturer defendants’ contention that the plaintiffs have failed to adequately allege “but for” causation is without merit, as the test for legal causation is proximate cause (see *Burlington Ins. Co. v NYC Tr. Auth.*, 29 NY3d 313, 57 NYS3d 85 [2017]). Similarly, the manufacturer defendants’ contention that plaintiffs have failed to adequately allege causation in a general sense is not dispositive herein. “Generally, issues of proximate cause are for the fact finder to

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resolve” (*Gray v Amerada Hess Corp.*, 48 AD3d 747, 748, 853 NYS2d 157 [2d Dept 2008], quoting *Adams v Lemberg Enters., Inc.*, 44 AD3d 694, 695, 843 NYS2d 432 [2d Dept 2007]). Even at the more advanced stage of litigation, “the absence of direct evidence of causation [does] not necessarily compel a grant of summary judgment in favor of the defendant, as proximate cause may be inferred from the facts and circumstances underlying the injury, the evidence must be sufficient to permit a finding based on logical inferences from the record and not upon speculation alone” (*Hartman v Mountain Val. Brew Pub*, 301 AD2d 570, 570, 754 NYS2d 31, 32 [2003]; see also *Schneider v Kings Hwy. Hosp. Ctr.*, 67 NY2d 743, 500 NYS2d 95 [1986]; *Mitchell v Mongoose, Inc.*, 19 AD3d 380, 796 NYS2d 421 [2d Dept 2005]). Here, the plaintiffs have adequately pled that the alleged breach of the manufacturer defendants’ duty herein was a proximate cause of their injuries.

Finally, the manufacturer defendants contend that the economic-loss doctrine bars the plaintiffs’ cause of action for negligence. The economic loss doctrine provides that economic losses with respect to a product and consequential damages resulting from an alleged defect in that product are not recoverable in a cause of action for strict products liability and negligence against a manufacturer (*New York Methodist Hosp. v Carrier Corp.*, 68 AD3d 830, 892 NYS2d 110 [2d Dept 2009]). A product may be defective due to a mistake in the manufacturing process, a negligent design, or a failure to provide adequate warnings regarding the use of the product (*Sprung v MTR Ravensburg*, 99 NY2d 468, 758 NYS2d 271 [2003]; *Gebo v Black Clawson*, 92 NY2d 387, 392, 681 NYS2d 221 [1998]; *Voss v Black & Decker Mfg. Co.*, 59 NY2d 102, 463 NYS2d 398 [1983]). “The rationale behind the economic loss doctrine is that economic losses resulting from a defective product are best treated under the law of contracts, not tort” (*Shema Kolainu-Hear Our Voices v ProviderSoft, LLC*, 832 F Supp 2d 194 [ED NY 2010]; see also *Hydro Invs., Inc. v Trafalgar Power Inc.*, 227 F3d 8, 16 [2d Cir 2000]). “This is because ‘[t]he particular seller and purchaser are in the best position to allocate risk at the time of their sale and purchase, and this risk allocation is usually manifested in the selling price’” (*Shema Kolainu-Hear Our Voices v ProviderSoft, LLC*, 832 F Supp 2d at 205, quoting *Bocre Leasing Corp. v General Motors Corp.*, 84 NY2d 685, 688, 621 NYS2d 497, 498 [1995] [internal citations omitted]).

“New York does not permit recovery through tort actions for damages that result from the poor performance of a contracted-for product” (*Shema Kolainu-Hear Our Voices v ProviderSoft, LLC*, 832 F Supp 2d at 205 [internal citations omitted]). It is well settled that a simple breach of contract is not considered a tort unless a legal duty independent of the contract has been violated (*Clark-Fitzpatrick, Inc. v Long Is. R.R. Co.*, 70 NY2d 382, 389, 521 NYS2d 653, 656 [1987]; see *New York Univ. v Continental Ins. Co.*, 87 NY2d 308, 639 NYS2d 283 [1995]; *Sommer v Federal Signal Corp.*, 79 NY2d 540, 583 NYS2d 957 [1992]). Here, the plaintiffs have not asserted a cause of action against the manufacturer defendants for breach of contract or an alleged defect in the product produced by said defendants. In addition, the plaintiffs’ allegations indicate that the relevant transactions between the parties were not contractual, that they did not afford the plaintiffs the opportunity to allocate the attendant risks associated with the alleged improper acts and omissions of the manufacturer defendants, and that this is more than a “case of economic disappointment” which would make the economic-loss doctrine applicable herein (see *Bellevue S. Assoc. v HRH Constr. Corp.*, 78 NY2d 282, 294, 574 NYS2d 165, 170 [1991]; see e.g. *Hydro Invs., Inc. v Trafalgar Power Inc.*, 227 F3d 8; *Assured Guar. (UK) Ltd. v J.P. Morgan Inv. Mgt. Inc.*, 80 AD3d 293, 915 NYS2d 7 [1st Dept 2010]). Accordingly,

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that branch of the manufacturer defendants' motion which seeks to dismiss the plaintiffs' seventh cause of action for negligence is denied.

Conclusion

In accordance with the foregoing analysis, the manufacturer defendants' motions are denied, except to the extent that the complaint against Allergan plc is dismissed for lack of personal jurisdiction. As to any contentions by the manufacturer defendants not specifically addressed above, the court finds that they lack merit or that they state defenses more appropriately considered on a motion for summary judgment or at the trial of this action.

The manufacturer defendants shall serve their answer(s) to the complaint within 10 days after the date on which this order is uploaded on the NYSCEF site (*see* CPLR 3211 [f]).

Dated:

June 18, 2018

Jerry Garguilo
J.S.C.
HON. JERRY GARGUILO